THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

Mitek's Reply In Support of its Motion For Summary Judgment
of Infringement and No Inequitable Conduct

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I. There Is No Question of Material Fact Precluding Summary Judgment of Infringement Under Mitek's Proposed Claim Construction

Except for two limitations, Arthrex does not dispute that FiberWire literally has every limitation of the asserted claims under either parties' claim construction. Arthrex tries to evade literal infringement of the "PE" limitation under Mitek's proposed construction by resorting to a legal doctrine that is, at best, on life support -- namely, the reverse doctrine of equivalents. Arthrex also tries to evade infringement based on the "consisting essentially of" language under Mitek's proposed construction by making arguments that are contrary to law, irrelevant, or totally unsupported. Such arguments fail to stave off summary judgment.

A. Arthrex Cannot Escape Literal Infringement By Resorting To A Doctrine That The Federal Circuit Has Never Upheld

As it cannot do so, Arthrex does not dispute that FiberWire literally has the claimed "PE" if "PE" is correctly construed to mean "any polymer formed from a repeating ethylene monomer (*i.e.*, all types of polyethylene including ultra high molecular weight polyethylene)." Rather, Arthrex tries to create a factual issue by resorting to the reverse doctrine of equivalents (Arthrex SJ Opp. at 8-9).[1] But this defense is so far-fetched that in 2002 -- in the only case Arthrex cites on the issue -- the Federal Circuit remarked that: "*[n]ot once has this court affirmed* a decision finding noninfringement based on the reverse doctrine of equivalents." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc*., 279 F.3d 1357, 1368 (Fed. Cir. 2002) (emphasis added).

In fact, after *Tate,* it is not clear whether the reverse doctrine of equivalents is even a viable defense. As the Federal Circuit explained, the reverse doctrine of equivalents is an "anachronistic exception, long mentioned but rarely applied." *Id.* The antiquated doctrine

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[1] Mitek cites to Arthrex's Opposition to Mitek's Summary Judgment Motion as "Arthrex SJ Opp." Mitek previously submitted Exs. 1-23 with its opening memorandum and attached them to its statement of undisputed facts, and has attached Exs. 24-30 hereto. Mitek cites its exhibits as "Mitek Ex.#" Mitek cites Arthrex's exhibits as "Arthrex SJ Opp. Ex. #."

predates the enactment of 35 U.S.C. §112, which imposes, *inter alia*, written description, enablement, and definiteness requirements that are co-extensive with the broadest possible reach of the reverse doctrine of equivalents. *Id.* Thus, according to the Federal Circuit, those statutory requirements may have supplanted the reverse doctrine of equivalents.

But even if the reverse doctrine of equivalents has any vitality, it is of no help to Arthrex because, on the present record, no reasonable trier of fact could find that FiberWire is "so far changed in principal" from the invention claimed in the 446 Patent. Arthrex has come forward with no evidence that could create a genuine dispute of material fact. The only evidence Arthrex presents is their own interrogatory responses (Arthrex SJ Opp. at 9). But Defendants' own contentions are inadmissible by Arthrex as evidence,[2] and certainly are not a basis for denying Mitek's motion.[3] Because Arthrex has failed to satisfy its burden[4] of producing admissible evidence that raises a genuine issue of material fact, Mitek's motion should be granted.

Nevertheless, even if this Court were to consider Arthrex's attorney assertion, Mitek's motion should still be granted because FiberWire operates in the same way as the invention claimed in the 446 Patent, not in "exactly the opposite" way, as Arthrex alleges (Arthrex SJ Opp. at 9). The 446 Patent teaches that "it is possible to tailor the physical and biological properties of

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[2] Arthrex's attorney contentions are inadmissible hearsay under F.R.E. 802, inadmissible for lack of competency under F.R.E. 601/602, and inadmissible unqualified expert testimony under F.R.E. 702. Mitek has submitted herewith a motion to strike Arthrex's inadmissible interrogatory responses.

[3] *Invitrogen Corp. v. Clontech Labs., Inc*., 429 F.3d 1052, 1068 (Fed. Cir. 2005) (holding that "[u]nsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony" and attorney argument "does not, and cannot, support Clontech's burden on summary judgment"); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1284 (Fed. Cir. 2005) ("[a]ttorney argument is no substitute for evidence"); *Glaverbel Societe Annoyme v. Northlake Mktg. & Supply, Inc*., 45 F.3d 1550, 1562 (Fed. Cir. 1995) (attorney argument is insufficient basis for denying summary judgment).

[4] *Smithkline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889-890 (Fed. Cir. 1988) (accused infringer has the burden of production with respect to the reverse doctrine of equivalents).

the braid by varying the type and proportion of each of the dissimilar fiber forming materials" (Mitek Fact 6; *see also* Mitek Fact 7). As Arthrex's vice-president and designer of FiberWire, Mr. Don Grafton, testified, this is precisely what Arthrex did in designing FiberWire – Mr. Grafton adjusted the type and amount of PE (*i.e.*, Dyneema) and PET (*i.e.*., polyester) until he arrived at a construction with optimal suture properties:

> Q. At this point in time, November 1998, *were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?*
> *A. During -- during the -- during that period of time, yes.*
>
> Q. *Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?*
> *A. Yes.*
> Q. Any other properties? Knot tiedown?
> A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
> Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
> A. Yes.

(Mitek Ex. 24 at 69:16-21; 70:4-13) (emphasis added).

Mitek's 446 Patent also describes the materials used in FiberWire, namely PE and PET, and their properties. Also, Mitek's 446 Patent describes the preferred embodiments of the claimed first set of yarns as "lubricating yarns" that act to improve "pliability or compliance, and surface lubricity," "nonabsorbable polymers," and "fiber-forming material[s]" (Mitek Ex. 1 at 4:9-15). Further, the 446 Patent describes more preferred embodiments, in which the second set of yarns imparts strength (*id*. at 4:33-36). Arthrex's liability expert, Dr. Mukherjee, and Mr. Grafton agree that FiberWire's PE is lubricous (Mitek Fact 134; Mitek Fact 29), and therefore, there can be no reasonable dispute that FiberWire's PE improves compliance and surface

lubricity. Also, as a lubricous material, FiberWire's PE contributes to handling and pliability properties because it permits fiber-to-fiber movement (Mitek Fact 164), just as the 446 Patent teaches (Mitek Fact 165). There is no dispute that FiberWire is not bioabsorbable (Mitek Undisputed Fact 19) and is fiber-forming. Further, as Mr. Grafton testified, FiberWire's PET improves the knot holding strength of FiberWire (Mitek Fact 141).[5] Thus, FiberWire operates in accordance with, not opposite to, the teachings of the 446 Patent, and no reasonable trier of fact could find that FiberWire is so far changed in principal that the reverse doctrine of equivalents applies.

B. The "Consisting Essentially of" Phrase Does Not Preclude Summary Judgment of Literal Infringement

Arthrex incorrectly argues that there is no infringement based on the claim language "consisting essentially of" because about one inch of either end of FiberWire is "tipped," FiberWire is coated, and TigerWire has a nylon marker for visual identification. But these arguments should be rejected because they are either legally erroneous, irrelevant, or totally unsupported.

1. Arthrex's Tipping Allegations Are Legally Erroneous and Not Supported By Admissible Evidence

Arthrex alleges that FiberWire does not infringe because about one inch of both ends of the about-38 or 18 inch long FiberWire sutures are "tipped" by adding an adhesive to the ends to prevent fraying and allegedly provide other characteristics (Arthrex SJ Opp. at 8) (FiberWire is

[5] Mr. Grafton testified that a braid of ultra high molecular weight PE was so lubricous it would not hold a knot, and the PET increased the ability to hold a knot (Mitek's Undisputed Facts 29-31). Because facing Mr. Grafton's admission kills Arthrex's argument, Arthrex tries to recast Mr. Grafton's admission by terming it "knot security" and asserting that it has nothing to do with "strength" (Arthrex SJ Opp. at 4). But this argument is nonsense. Arthrex's expert, Dr. Mukherjee, admits that knot holding strength is determined by measuring the knot failure by slipping or breaking (Mitek Ex. 25 at 233:9-234:6). Further, Mr. Grafton, consistent with Dr. Mukherjee and Mitek's expert, Dr. Brookstein (Mitek Ex. 26 at ¶14, n.1), admitted that knot security includes a strength, namely the resistance to slippage (Mitek Ex. 24 at 31:22-32:4).

38 ins. long. Mitek Ex. 27 at 13-1.). But Arthrex's argument is legally erroneous. As long as 36 or 16 inches of FiberWire infringes, it is irrelevant whether FiberWire's ends infringe. *Suntiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999) (holding that the "district court's error lies in the fact that we have never required that a claim read on the entirety of an accused device in order to infringe"); *A. B. Dick Co. v. Burroughs Corp*., 713 F.2d 700, 703 (Fed. Cir. 1983) (holding that inclusion of an infringing device into a larger device does not escape infringement). As the Federal Circuit has explained, "a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write." *Id*. at 703.

Arthrex's argument also fails because Arthrex has failed to come forward with any admissible evidence with respect to tipping. Rather, Arthrex cites to its own inadmissible attorney contentions in defendants' interrogatory responses (Arthrex SJ Opp. at 8) (*see supra*, n.2). Having failed to come forward with any admissible evidence, Arthrex has not raised any genuine issue of material fact. *See supra*, n 3.

2. FiberWire's "Coating" Does Not Raise Any Genuine Issues of Material Fact

Arthrex's only argument with respect to coating is that FiberWire's PET improves "knot tying ability" and FiberWire's coating purportedly has a material effect on knot tying ability (Arthrex SJ Opp. at 6). But this allegation and Arthrex's response to Mitek Facts 33-38 are irrelevant. As properly defined, the novel and basic characteristics of the invention are "a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from a second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid." Thus, the question is whether FiberWire's coating materially affects the

dissimilar yarns, namely PE and PET, from *contributing different properties*, not whether the coating materially affects *any property*. Tellingly, Arthrex provides no evidence that FiberWire's coating affects FiberWire's braided PET and PE from being a heterogeneous braid of dissimilar, non-bioabsorbable yarns in direct intertwining contact, and providing different properties that contribute to the overall braid properties.

But even if "knot tying ability" had any relevance, Arthrex's allegations still fail because they are unsupported. Arthrex cites to Dr. Brookstein's expert report at ¶15 as its only support for the argument that PET improves "knot tying ability" (Arthrex SJ Opp. at 6). But Dr. Brookstein's report at ¶15 discusses *knot holding strength* (Arthrex SJ Opp. Ex. 13 at ¶15), which Dr. Brookstein defines as the "force at which a knot fails by slipping, elongating to a certain extent, or breaking" (Mitek Ex. 26 at ¶14, n.1), not "*knot tying ability*." Thus, Arthrex's allegations are unsupported and fail.

Recognizing that it lacks any evidence, Arthrex resorts to criticizing Mitek's position (Arthrex SJ Opp. at 6-7). But Arthrex's colorful criticism is unwarranted because the 446 Patent specifically teaches that monofilament-like coatings may have a material effect (Mitek Ex. 1 at 1:20-25), but that other coatings, like FiberWire's surface coating, are immaterial or optional (*id.* at 6:5-8). Arthrex also criticizes Mitek's position as just a restatement of the "direct intertwining contact" limitation (Arthrex SJ Opp. at 7). But again, that is false because a suture could have yarns braided in direct intertwining contact, yet have a monofilament-like coating that could potentially materially affect the basic and novel characteristics (Arthrex SJ Opp. Ex. 4 at 399:6-8). Further, even giving Arthrex the benefit of the doubt, it is proper to glean the basic and novel properties of the invention from the claims and the specification. *See, e.g.*, *AK Steel, Corp. v. Sollac*, 344 F.3d 1234, 1239-40 (Fed. Cir. 2003) (when specification clear on novel and basic

characteristics then determining what that means is claim construction issue for the court); *BASF Corp. v. Eastman Chem. Co.*, No. 95-746-RRM, 1998 U.S. Dist. LEXIS 23054, *24-*30 (D. Del. Mar. 24, 1998) (basic and novel characteristics derived from the specification and claim language) (Mitek Ex. 28); *Momentus Golf, Inc. v. Swingrite Golf Corp.*, 312 F. Supp. 2d 1134, 1140-1141 (S.D. Iowa 2004) (basic and novel properties discerned from patent claims), *rev'd on other grounds.*, No. 05-1614, 2006 U.S. App. LEXIS 16665 at *3, *9-*10 (Fed. Cir. June 30, 2006) (unpublished) (Mitek Ex. 29) (vacated and remanded because district court erred in finding a disclaimer attached to amendment adding "consisting essentially of" language and erred in relying on ambiguous statements in prosecution history for disclaimer).

3. TigerWire's Nylon Does Not Materially Affect the Basic & Novel Characteristics

Arthrex half-heartedly asserts in a footnote that TigerWire's inclusion of one black nylon yarn –which undisputedly is for visual identification of TigerWire as a black and white striped suture (Mitek Undisputed Fact 39) -- for one of the eight PET yarns has a material effect on the novel and basic characteristics as defined by Mitek (Arthrex SJ Opp. at 7, n.5). Because Arthrex cannot dispute that the nylon does not materially *affect the dissimilar yarns from providing different properties*, it tries to miscast the issue. As it did with its coating argument, Arthrex alleges that the nylon yarn affects *certain suture properties* (strength and pliability), not whether it has any effect on the *dissimilar yarns (i.e., FiberWire's PE and PET) from providing different properties*. Nevertheless, Arthrex's argument fails because Arthrex does not even assert that there is a "material effect," but rather merely only asserts that "nylon affects" properties (*id.*). The only relevant issue is whether there is a material effect; non-material effects are not relevant. *PPG Indus. v. Guardian Indus. Corp.*, 156 F. 3d 1351, 1354-55 (Fed. Cir. 1998).

Also, Arthrex lacks sufficient evidence from which a reasonable jury could find that the nylon has any effect on the basic and novel characteristics of the invention. According to Arthrex, Dr. Mukherjee opined that the nylon increases strength at pages 30-31 of his expert report. But Dr. Mukherjee's expert report has no mention whatsoever of nylon affecting "strength" (Arthrex SJ Opp. Ex. 6 at 30-31). Further, Arthrex cites to Dr. Mukherjee's "drape" and "feel" tests and opinion about nylon properties for the position that the inclusion of one nylon yarn affects pliability (Arthrex SJ Opp. at 7, n.5). But at his deposition, Dr. Mukherjee admitted that he did not perform tests with TigerWire, and only saw TigerWire sutures (Mitek Ex. 25 at 515:11-516:5; 122;7-124:17), the drape test is not a scientifically acceptable method (*id*. at 509:16-20; 513:12-16), and the literature upon which he relied for nylon was erroneous because it was for nylon molding compound, not nylon in fiber form, as is used in sutures (*id*. at 475:25-477:10).[6] In any event, Dr. Mukherjee's assertions are irrelevant because at no place does he opine that nylon materially affects TigerWire's PE and PET from contributing dissimilar properties, which is the salient issue. Arthrex is left with no evidence to create a genuine issue of a material fact that requires submitting to the jury.

C. Arthrex Cannot Escape Literal Infringement

Arthrex has tried to escape literal infringement by reaching to the bottom of the barrel of legal arguments and trotting out the reverse doctrine of equivalents. But that is of no help to it here because that doctrine has questionable legal vitality, and no reasonable trier of fact could find that it applies based on the undisputed evidence. Arthrex has also made erroneous legal arguments regarding "tipping" that should be rejected outright as contrary to age-old law. Finally, Arthrex has tried to escape infringement by relying on FiberWire's coating and

[6] Mitek has submitted herewith its motion to strike Dr. Mukherjee's opinions regarding TigerWire's pliability and nylon because he did not do the tests and his analysis is junk science.

TigerWire's nylon marker band, but the only record evidence is that none of these has a material effect on the novel and basic characteristics as defined by Mitek.

II. There Is No Question Of Material Fact Precluding Summary Judgment of No Inequitable Conduct

Try as it may to trump up an inequitable conduct argument, Arthrex has utterly failed. Arthrex cannot even show that a misrepresentation was made, much less a material one. Further, Arthrex improperly relies on a "gross negligence" standard that was overruled years ago, and has failed to show the requisite threshold level of intent by clear and convincing evidence. Summary judgment should be granted in Mitek's favor.

A. Arthrex's Inequitable Conduct Allegations Should Be Dismissed Because They Are Based On An Overruled "Gross Negligence" Standard

Citing to *Reactive Metals & Alloys Corp. v. ESM, Inc.*[7], Arthrex incorrectly asserts that "gross negligence may constitute sufficient wrongful intent to support a holding of inequitable conduct" (Arthrex SJ Opp. at 10), and that there is inequitable conduct because Ethicon allegedly acted with gross negligence (Arthrex SJ Opp. at 14-16). But, as the Federal Circuit has held since 1988, "gross negligence is not, in and of itself, sufficient to satisfy the intent element of inequitable conduct." *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1148 (Fed. Cir. 2003) *citing Kingsdown Med. Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). Significantly, the Federal Circuit expressly stated that the antiquated 1985 *Reactive Metals* case and its "gross negligence" standard have been overruled: "To the extent that *Reactive* suggested that a finding of gross negligence standing alone is sufficient to satisfy the intent prong of inequitable conduct, *it has been overruled* by the *en banc* portion of our decision in *Kingsdown*, 863 F.2d at 876 (en banc in relevant part)." *Id.* at 1148, n.6. (emphasis

[7] 769 F.2d 1578 (Fed. Cir. 1985).

supplied). Thus, Mitek's motion should be granted because Arthrex's defense is predicated on an erroneous legal standard.

B. Mitek's Motion Should Be Granted With Respect to Kaplan Because Arthrex Cites No Law Supporting A Finding of Inequitable Conduct Under These Facts And Relies on Unsupported Conjecture

Arthrex refers to its arguments with respect to the Kaplan reference as a "garden variety" case of inequitable conduct (Arthrex SJ Opp. at 11). But Arthrex's inability to cite even one case holding that inequitable conduct has been committed by merely arguing about the teachings of a disclosed reference is a tacit admission that there was no inequitable conduct. Also, tellingly, Arthrex is unable to distinguish the cases cited by Mitek where courts have consistently held that there is no inequitable conduct where the allegations are based on a reference that the Patent Office has undisputedly considered and nothing was withheld (Mitek Opening SJ Br. at 21-22).

Arthrex's arguments with respect to Kaplan should also be rejected as lacking any supportable evidence, much less clear and convincing evidence. Arthrex basically asserts that Kaplan teaches something different than what Mr. Woodrow explained to the Patent Office and the Patent Office found to be true. But Arthrex's position is unsupported by any expert testimony, and relies on mere attorney argument about Kaplan's teachings (Arthrex SJ Opp. at 15-16). As attorney conjecture is no substitute for admissible expert testimony, Mitek's motion should be granted (*see supra*, n.3).

Arthrex's opposition provides a prime example of why attorney argument regarding a technical reading of a reference is inadmissible and perhaps why Arthrex's technical expert did not opine on this issue (Mitek Undisputed Fact 109, 110). Arthrex's counsel asserts that Kaplan teaches a completely nonabsorbable sheath, but omits from its citations –including lines interspersed between its citations -- Kaplan's repeated statements that the sheath is bioabsorbable or semiabsorbable (Arthrex SJ Opp. Ex. 25 at 2:26-28; 2:31-36; 2:36-41; 2:66-3:4; 2:55-58;

2:62-65; 3:66-3-68; 7:13-62; 9:10-12). Arthrex also improperly cites to Kaplan's discussion of "filaments" as being a discussion of yarns (*id.* at 9:25-28).

Mitek's motion should also be granted with respect to Kaplan because Arthrex has absolutely no evidence of intent to deceive. As explained in Mitek's opening memorandum, Mr. Woodrow testified that Kaplan is distinguishable for the same reasons as expressed before the Patent Office (Mitek Fact 108). Arthrex relies on mere attorney argument that he must have thought something different. But such conjecture does not meet the requisite threshold level of intent to deceive. *Juicy Whip, Inc. v. Orange Bang, Inc*., 292 F.3d 728, 744 (Fed. Cir. 2002) (reversing inequitable conduct finding where infringer failed to present any evidence that applicants considered anything said to the Patent Office to be untrue or misleading).

C. Arthrex Has Failed To Show a Misrepresentation or Intent to Deceive With Respect to Burgess

As Arthrex has failed to identify any inconsistent belief held by Dr. Steckel, Arthrex's allegations regarding Burgess are baseless. Further, the record is devoid of any evidence of intent to deceive.[8]

1. Arthrex Has No Evidence of a Misrepresentation Regarding Burgess

Arthrex incorrectly alleges that Dr. Steckel's testimony at pages 189:19-190:5 is inconsistent with the statements that (i) "the fishing line of Burgess would have poor knot strength properties because of its braided construction;" (ii) "the property requirements for fishing line yield a braid with poor knot strength and security;" and (iii) even if a medical designer "did use the teachings of the fishing line art to modify a suture then he would inevitably design an unacceptable suture" (Arthrex SJ Opp. at 2, 13). But tellingly, Dr. Steckel's cited

[8] Arthrex tries to spin Mr. Witherspoon's, its patent law expert's, fatal admission that he could not say that a duty of candor had been violated (Arthrex SJ Opp. at 13-14, n.7). But his testimony was clear that he refused to provide such an opinion (Mitek Fact 120).

testimony is not about Burgess, fishing line, any property requirements for fishing line, knot strength or security properties of Burgess or fishing line, or what a medical designer would do based on the teachings of fishing line art. Rather, it is about sutures (Arthrex SJ Opp. Ex. 5 at 189:19-190:24). In fact, Arthrex admits that there is no evidence that Dr. Steckel was familiar with fishing line properties or considered designing sutures from fishing lines (Mitek Undisputed Facts 116-117). Thus, Arthrex's inequitable conduct argument with respect to Burgess should be dismissed for failing to point out any inconsistency, much less a material misrepresentation.[9] *Juicy Whip, Inc.* 292 F.3d at 745-46 (setting aside inequitable conduct because infringer failed to show any statement that was inconsistent or wrong).[10]

2. Arthrex Has Failed To Show The Requisite Threshold Level of Intent Regarding Burgess

Arthrex fails to cite to any testimony from Dr. Steckel or Mr. Goodwin, the prosecuting attorney, that they had any intent to deceive. Left with no relevant evidence, Arthrex alleges that Dr. Steckel thought something that was the "exact opposite" of what Mr. Goodwin stated

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[9] Arthrex incorrectly asserts that Burgess discloses a certain braided combination of UHWMPE and PET (Arthrex SJ. Opp. at 11, 12). Arthrex's statements regarding the supposed teachings of Burgess are just attorney assertion unsupported by any expert testimony. Although Mitek disputes Arthrex's assertions based on Dr. Hermes reading of Burgess (Mitek Ex. 30 at ¶¶88-93, 104-106, 111-113, and 117), those issues are not relevant here because the relevant issue as Arthrex has framed its contentions is whether the statements in the office action response were inconsistent with Dr. Steckel's beliefs.

[10] Arthrex cites three cases as being analogous to the facts with respect to Burgess. But none of them have applicability here. *Hoffman-La Roche, Inc. v. Roche Molecular Sys., Inc.*, 323 F.3d 1354, 1361, 1366, 1371 (Fed. Cir. 2003) (reversing finding of inequitable conduct where inventors believed that they allegedly withheld information relating to a "Stoffel Experiment" was immaterial, and affirming inequitable conduct only where the applicants had misrepresented that they had performed "Example VI" and achieved certain results when they had not, and had misrepresented their knowledge about the prior art, and there was testimony from a witness showing that the inventor knew something that was withheld); *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1378-79 (Fed. Cir. 2000) (patent attorney failed to disclose to Examiner that Patent Office Board had previously decided the very assertions he was making against the applicant); *Rohm & Hass Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1570 (Fed. Cir. 1983) (holding that inequitable conduct had been committed where applicant admittedly made false and misleading statements).

(Arthrex SJ Opp. at 14). But Arthrex provides no citation to the record and no evidence that Dr. Steckel thought anything opposite to the statements about Burgess or fishing lines (*id.*). Arthrex also cites to the fact that Dr. Steckel was Mr. Goodwin's primary contact in preparing the patent application, and that Mr. Goodwin received comments on an office action from a different inventor, Mr. Hunter, who has been deceased for many years (*id.*). But these facts are present during the prosecution of almost any patent application, and they fail to show any intent to deceive.[11] Here, on summary judgment, Arthrex had the burden to come forward with *prima facie* clear and convincing evidence of a threshold level of intent to deceive to create a genuine dispute of material fact for trial.[12] But Arthrex has failed to do so, and summary judgment is warranted in Mitek's favor.[13]

III. Conclusion

Arthrex has tried to stave off summary judgment of infringement by citing to an antiquated legal doctrine, asserting an erroneous legal proposition, and making arguments that are irrelevant or lack any evidentiary foundation. Likewise, Arthrex has tried to justify its meritless inequitable conduct charges by citing to law that was overruled in the 1980's and

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[11] Also, Arthrex's assertion should be dismissed because it is inappropriate to argue an adverse inference based on a privileged communication. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1345 (Fed. Cir. 2004) ("courts have declined to impose adverse inferences on invocation of attorney-client privilege").

[12] Nor can Arthrex rebut the fact that Dr. Steckel thought he had disclosed ultra high molecular weight PE in his patent application and nothing was withheld except by calling him a liar (Arthrex Opp. Br. at 12, n.6). But Arthrex lacks any evidence to support this baseless accusation and attack on Dr. Steckel's character.

[13] *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1322 (Fed. Cir. 2006) (affirming JMOL of no intent where infringer merely argued that the applicant or his attorney knew, or should have known that withheld information would be material); *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1358-59 (Fed. Cir. 2003) (affirming no inequitable conduct where threshold level of intent not shown); *Juicy Whip, Inc.* 292 F.3d at 745 (setting aside inequitable conduct finding in part because of lack of evidence establishing a threshold level of intent); *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1384 (Fed. Cir. 1998) (reversing finding of inequitable conduct where threshold level of intent not shown).

relying on unsupported attorney argument. As Arthrex has failed to come forward with evidence showing that a reasonable jury could find for it on either the infringement or the inequitable conduct issues, Mitek's motion should be granted.

Date: September 15, 2006

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By its attorneys,

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of:

Mitek's Reply In Support of its Motion For Summary Judgment of Infringement and No Inequitable Conduct

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Dated: September 15, 2006

_/s/ Erich M. Falke_____
Erich M. Falke

MITEK EXHIBIT 24

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

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A. I said they are related.
Q. Okay. They're your terms. I just want to understand them because when we ask questions, I want to make sure we're both on the same page, because there's a lot of terms that we're throwing around, and some people have different definitions and some people have different understandings of what they mean, so I want to know that when I ask you a question and I ask you a question about knot tiedown that we're both talking about the same thing so there's no misunderstanding what we're talking about.
A. I've told you they were closely related.
Q. Right. But closely related doesn't tell me what knot tiedown is in your mind, so I'm trying to figure out what it means in your mind. So now I've heard you say that it's the ability to approximate the tissue and hold it in place through biomechanical forces?
A. (Witness nods head affirmatively).
Q. I heard you say the size of the knot bundle is part of knot tiedown?
A. (Witness nods head affirmatively).
Q. And by size of the knot bundle, you are referring to how big the knot is when it's tied?
A. Correct.
Q. Anything else included within knot tiedown in your mind?

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A. Not that I can think of right now.
Q. Okay. So in evaluating the Tevdek suture, did you evaluate the Tevdek suture for knot tiedown characteristics?
A. Evaluated for knot strength and straight pull.
Q. How about knot tiedown characteristics?
A. There is no test report that would have knot tiedown as -- as part of the characteristics that were tested.
Q. You said there's no test report. And my question -- that does not necessarily answer the question.
MR. SOFFEN: I think he answered it no at the beginning of the answer.
Q. That's not what the record says.
A. I told you it was a term that we didn't use directly. Knot tiedown -- "knot tiedown" was not used. So the answer to your question then is no.
Q. No? Okay. How about the Pearsalls suture that was polyester? Was that evaluated for knot tiedown characteristics?
A. No.
Q. Okay. How about the term "knot security"? Are you familiar with that term?
A. Yes.
Q. What does knot security mean to you?

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A. The ability of the knot to not slip and to maintain the inner loop linear section that was tied with the knot and hold -- and maintain that during biomechanical forces without slippage.
Q. What do you mean by the inner loop linear section of the knot?
A. When you tie a knot, you're tying it most of the time to bone and tissue. There's -- If you tie a knot, then there's a loop; okay? The knot slippage would be measured as an increase in that loop diameter.
Q. Is there a standard test for that?
A. What do you mean standard test?
Q. A test -- Well, let me rephrase the question.
A. Is there any test for it? Or I don't understand the question.
Q. Let me rephrase the question. Was there a test that you are familiar with that you generally used to evaluate knot security?
A. Not generally. It was tested, but -- but not every time.
Q. And what test was that?
A. There -- the -- What test?
Q. Right.
A. The test for the slippage of the knot.
Q. And how was that test conducted?

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A. Pull tested with the inside i.d. of the suture held and measured the strength before the increase in size of the inner loop.
Q. What type of machine was used for that?
A. Tensile test machine.
Q. Would you draw a picture of that test.
A. (Witness complying).
Q. Okay. Can you label the components you've drawn.
A. (Witness complying).
Q. And can you describe what you have labeled -- I see you have labeled the crosshead, two hooks, the knot, and a suture loop; right?
A. Yes.
Q. Okay. And the forces applied by -- Well, what type of machine is this? I'm sorry. This is a tensile test?
A. Tensile test.
Q. And force is applied to pull from each direction, top and bottom, if you will?
A. That's what the two arrows signify.
Q. Okay. Are there mandrels which that knot -- around that suture loop? Does the suture loop go around mandrels?
A. Hooks or pins or some way to affix the suture. So when you say a mandrel, I mean there's a lot of

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decitex?
A. No. No, I can't remember that.
Q. Do you recall evaluating any samples that had Dyneema 400 denier or higher?
A. No.
Q. Do you think you did or you just don't recall?
A. I received -- I'm sure I received the samples. What I did with them, I don't recall.
Q. Okay. How long -- how much before this letter do you think you came up with the idea to use the ultra-high molecular weight polyethylene with PET blended together?
A. Whatever the Chicago National Sales Meeting was. The flight just before the start date would be the time that I came up with the idea. I don't know what that time is. I just remember the circumstance.
Q. You say Chicago National Sales Meeting?
A. That's correct.
Q. Is that Arthrex National Sales Meeting?
A. Yes.
Q. Was that a meeting with all the Arthrex sales reps.?
A. That's correct.
Q. And it was sometime before the July -- It was the meeting before the July 10, 19 -- I'm sorry. The meeting where you came up with the idea was the meeting before the

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July 10th, 1998 date on this letter?
A. Yes.
Q. I show you DePuy Mitek Exhibit 324. Do you recognize Exhibit 324 as a letter from you to Mr. Hallett?
A. I don't recall the letter, but I recognize my name and the contact person. But the specific circumstances of the letter, I don't remember.
Q. Based on your prior testimony, is it then true that this letter was after you came up with the idea and after you evaluated the prototype?
A. Yes. After I came up with the idea, yes.
Q. Okay. Was this letter sent before or after you came up with the -- I'm sorry. Was this November 16th, 1998 letter sent before or after you came up with the -- Sorry. I will rephrase the question.
Was the November 16th, 1998 letter, Exhibit 324, sent before or after you evaluated the prototype of ultra-high molecular weight polyethylene braided with PET?
A. I don't recall.
Q. When you had the prototype of PET and ultra-high molecular weight polyethylene made, do you know if Pearsalls specifically made that or if they just pulled it off their line from something else?
A. I'm sure they made it.
Q. They specifically made it?

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A. Yes.
Q. It's not like they had a product that they could just give to you?
A. No.
Q. In your letter, you say you tested the samples of Dyneema. Do you see that?
A. Yes.
Q. And then you say, "Can you build a 25 percent Dyneema/75 percent polyester blend in Size 2 that is very flexible (like the existing suture or the Ethicon sample) and send it to me to test"; do you see that?
A. Yes.
Q. Does that Ethicon sample, does that refer to an Ethibond?
A. Yes.
Q. And you say, "If we get the" -- "If we can get this blend correct, we will have a terrific advancement in suture for our soft tissue anchors"; do you see that?
A. Yes.
Q. What did you mean by that?
MR. SOFFEN: Objection; vague. It states what it states. What's the question?
Q. Do you understand the question?
A. I'm not sure what -- what you're asking.
Q. I would like to know what you mean by in your

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letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement."
What did you mean by "If we can get this blend correct"?
A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively).
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get the optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?

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A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
A. Yes.
Q. Were the product samples that were being made at this time in November of 1998, around this time, were they being made on a carrier braid machine?
A. Yes.
Q. I show you DePuy Mitek Exhibit 325. It's a letter dated November 16th, 1998 from Mr. Hallett to you. Do you see that?
A. Yes.
Q. Do you recall receiving this letter?
A. No.
Q. It says -- Mr. Hallett says in the letter, "Please find enclosed a matrix of information of the

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samples that you took with you on your visit to Pearsalls. I will endeavor to proceed with the existing trial to match the US2 Excel Braid made by Ethicon, in polyester construction." Do you see that?
A. Yes.
Q. Did you pick up the samples from Pearsalls that are mentioned in this --
A. I don't recall.
Q. Do you recall whether they were actually -- Do you recall going over to Pearsalls and having them actually make samples while you were there?
A. Yes.
Q. And were these samples -- These aren't samples they pulled off the line? These are samples where they took yarns and braided them according to what you guys were considering?
A. Repeat the question again.
Q. Sure. I'm just trying to get the sense of whether the samples that you picked up while you were at Pearsalls that you saw being made, were they -- was it an existing product they were picking up off the product line, or was this -- you know -- yarns that were selected and braided and going through the manufacturing process that you particularly picked out?
A. The latter.

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Q. Do you see under the yarns the first one is Dyneema?
A. Yes.
Q. And is has a DT number. Do you see that?
A. DT.
Q. Dt-no. Does that stand for DT number?
A. Where -- where do you see DT?
Q. The second column.
A. At the top as the heading, yes.
Q. Okay. Are you familiar that Pearsalls uses the terminology DT number for samples?
A. I don't recall what they use.
Q. You don't recall? Okay.
Was it the first sample -- Do you see where the first one is Dyneema and the second ones are Polys, the second through fourth are Poly/Dyneema? Do you see that?
A. Yes.
Q. Was the first sample of yarn here all Dyneema?
A. Evidently.
Q. Do you see in the second through the fourth yarns were a braided blend of Polyethylene and Dyneema?
A. Yes.
Q. Do you see the straight pull column?
A. Yes.
Q. I'm sorry. I may have misspoke.

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The second through fourth yarns that are listed, the Poly/Dyneema, is that -- are they Polyester and Dyneema?
A. Yes.
Q. Not polyethylene and Dyneema?
A. It's ultra-high molecular weight polyethylene and PET.
Q. Okay. Do you see the column straight pull?
A. Yes.
Q. Do you know what that means?
A. Testing that they did in their lab with their tensile test machine in kilograms.
Q. Is that with a knot or without a knot?
A. That's without a knot.
Q. Okay. And do you see how the Dyneema one was 23.12 kilograms?
A. Yes.
Q. And Poly/Dyneemas were on the order of 34 to 36 kilograms?
A. Yes.
Q. Do you know why the difference in strength between the Dyneema one and the other ones?
A. You can't tell by looking at this report why there's a difference.
Q. And you don't remember?

MITEK EXHIBIT 25

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

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The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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Q. How about a Tara Shaneville (ph), I think it is, did you ever speak with her?
A. No, thought that I can --
Q. How about Don Grafton?
A. I knew Don Grafton before this case, but during this case, I didn't spoke -- speak to him.
Q. Okay, all right. Why did you speak with Mr. Benavitz?
A. I saw him at the Academy of Orthopedic Surgeons meeting, and I believe I looked at the FiberWire suture or -- FiberWire suture, that's all. I don't remember exactly what I spoke, but I am more interested in just to know what products they have.
Q. Well, you referenced him in one of your reports, that you had spoken with him, so --
A. Yeah.
Q. -- what conversation did you -- had you had with him regarding this case?
A. Tell me where I said that.
Q. It's in your responsive report at page 5.
A. This is 239?
MR. TAMBURO: 240.
THE WITNESS: 240?
BY MR. BONELLA:

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Q. Page 5.
A. Page 5.
Q. Section 3, Review and Use of Documents and Other Materials, third line from the end of that section.
A. If my memory serves me right, I think I looked at the -- again, I'm not sure, the FiberWire -- I mean, the Tiger (ph) suture, if I remember correctly, that's where I saw it, and that's all. I probably did -- I don't know whether I did any lab test or anything like that, I don't remember exactly. That was very small conversation, less than five minutes.
Q. So, you spoke -- I'm getting confused. Your conversations with Benavitz, you're talking about the one you had with relevance to this case as opposed to the discussion you had at the conference?
A. Well, that's the discussion at the conference.
Q. Is the one you're referencing?
A. That's what I'm talking about, yeah.
Q. Okay. And was that academy conference, is that March 22nd?
A. Academy of Orthopedic Surgeons meeting,

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yeah --
Q. March 22nd?
A. -- in Chicago, yes.
Q. Of this year?
A. Uh-huh.
Q. And what -- do you recall what you discussed with him?
A. Again, I -- you know, I remember, you know, just -- I'm only interested in their products, what they have, because we are interested in doing orthopedic evaluation of their products.
Q. So, what do you remember about your discussion with him?
A. That's all I remember, that --
Q. Did anything you discussed with him form or impact your opinions at all?
A. No.
Q. Okay. Did you ever speak with Mr. Witherspoon?
A. Yes, I did.
Q. Okay. How long did -- how many conversations did you have with Mr. Witherspoon?
A. I think couple of times.
Q. Couple of times, two to three?
A. About that.

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Q. Okay. And how long were those conversations?
A. It could be half an hour, 45 minutes, or maybe less. I don't remember.
Q. And what were those discussions about?
A. Well, he was helping me with the legal side of this, and that's what was expressed in my report. The legal part came from him.
Q. He was helping you understand the legal framework?
A. I don't understand, but what he described to me, yes, I did.
Q. So, he was helping you understand the legal context for your report?
A. Some -- some things that, you know, that he went over, um-hum, yes, I understood.
Q. Okay. And developing this report, your three reports, did you speak with the lawyers from Mr. Tamburo's firm?
A. Yes, I spoke to Mr. Saber and Mr. Tamburo several times.
Q. How about Mr. Soffen, did you ever speak with him?
A. In the beginning, yes.
Q. Okay. So, you have met Mr. Soffen?

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sure, because he talks about other things, too, nylon --
BY MR. BONELLA:
Q. Right.
A. -- you know, ultra-strong polyethylene, polypropylene. So, he says, "In this study, we evaluated ultra-strong polyethylene fibers in comparison with nylon, polypropylene and polyester ophthalmic sutures."
So, I cannot say, like you said, that he wanted to get just like silk.
Q. Well, wasn't that -- wasn't that the ideal goal? Wasn't that what he was trying to do, because he looks at nylon -- let me back up.
About nylon he says, in column 2, about halfway down, he says, "Subsequently, 25 micrometer black-dyed nylon was provided by manufacturers," right? But then he goes on and says, "Although handling and knot-tying nylon sutures is more difficult because they are less flexible, more elastic, and smoother than silk, surgeons soon adapted to these characteristics," right?
A. Yeah.
Q. So, he recognizes some draw-backs of nylon

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sutures, right?
A. Yes.
Q. So, wasn't he trying to develop an ultra high molecular weight polyethylene suture that had good flexibility yet good strength?
MR. TAMBURO: Objection. To the extent he's asking -- you're asking the witness to opine on what the author is conveying in this article, I would ask the witness to read the entire article rather than the six lines of the six pages that you're pointing to.
THE WITNESS: He is trying to get a -- a suture out of ultra-strong -- ultra high polyethylene which will be acceptable for the ophthalmic surgical use.
BY MR. BONELLA:
Q. And the idea was to have it very flexible, yet strong, right?
A. Yes.
Q. Okay. I'd like to go to the Table 2 on page ARM 25135.
A. Yeah.
Q. It refers to knot holding strength.
A. Yes.
Q. Do you see that?

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A. Yes.
Q. Do you understand the tests that Cohan did to determine the knot holding strength?
A. I know what knot holding strength is, yes.
Q. Okay. What's your -- what is it?
A. That you tie a knot or certain knot configuration and you just pull it and see where -- now, the knot breaks, that gives the knot pull strength. Now, knot holding strength is different than the knot pull strength, and -- I mean, in general, I'm not exactly clear how he measured the GPa, the -- gigapascals, he has to know the load and the area and how much it slipped.
So, I'm not sure what these -- these figures, knot holding strength, means and how it was measured. I mean, holding strength, I can understand the numbers as they go up, they are better, like 4 and 4 is 0.65, 1.30, and that's close to knot pull strength, that's the ideal condition in that Table 2.
Q. If you go to page ARM 25133 --
A. Yeah.
Q. -- and go to the section on mechanical testing. Do you see that at the top?

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A. Yeah.
Q. Do you see that (indicating)?
A. Right here.
Q. Okay, and go to the next column over, first full paragraph. It says, "A third series of stress-strain curves was obtained."
Do you see that?
A. Yes.
Q. Cohan says, "was obtained by loading a specimen of two segments of a fiber joined by a knot. It was prepared from a single continuous fiber by first tying a knot of the configuration to be tested around a tube and then cutting the loop thus formed, yielding a specimen of two strands joined by the knot. These stress-strain curves give an indication of the security of that particular knot configuration with that fiber; knot holding strength is the end point, the point at which the knot breaks or slippage through the knot is observed."
Do you see that?
A. Yes.
Q. Okay. Now, reading that, do you have an understanding of what Cohan was -- did to determine the knot holding strengths in Table 2?

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A. Yeah, you know, the -- some knots slipped; some knots actually broke at the knot. So, when he calculated the knot pull strength, did he exclude those slipped? That's one possibility. So, that gives you the knot holding strength different from knot pull strength.
Q. Okay.
A. But the -- yeah, go ahead.
Q. Do you see where he says knot hold strength in Table 2?
A. Table 2, that's what I'm looking at.
Q. Right, and he has a section different than the knot pull strength?
A. Yes.
Q. And if you look at the -- the first column, he has a material. Do you see that?
A. Yes.
Q. Do you understand the material there to refer to a monofilament suture of a certain material?
A. Yes.
Q. Okay. So, the first one was polyethylene. Do you see that?
A. That's the ultra high molecular weight polyethylene.

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Q. Right. And the next suture was a nylon suture?
A. Yes.
Q. And the next one was a polypropylene suture?
A. Yes.
Q. And the final one was a polyester suture, right?
A. Yes.
Q. Okay, the next column is two equals two. Do you see that?
A. Yeah.
Q. Do you understand what that means?
A. I used to know. This is how you -- you actually put the suture knot together.
Q. It's the knot configuration, right?
A. Yes.
Q. It's a two equals two knot configuration, right?
A. Yeah.
Q. Okay. In the first column, there is no value for the ultra high molecular weight polyethylene, but there's values for the nylon, polypropylene and polyester.
Do you see that?

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A. Right.
Q. Did you understand when you read Cohan that there was no value for the polyethylene because it slipped and failed so easily in the two equals two configuration that it didn't register a value?
A. Most possibly, yes.
Q. Okay. And the three equals two equals one configuration, do you see that?
A. Yes.
Q. And the polyethylene has a value of 0.32 for that on holding strength, right?
A. Yes.
Q. Which is less than the knot holding strength listed for nylon, propylene and polyester for the three equals two equals one configuration, right?
A. Yes.
Q. Okay. So, you understand for the three equals two equals one configuration that the author was saying the polyethylene suture failed at a lower knot strength because it slipped?
A. Knot strength?
Q. Knot holding strength.
A. Okay.
Q. It failed at a lower knot holding

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strength --
A. Yes.
Q. -- the polyethylene, because it slipped.
A. Yes.
Q. So, the polyethylene suture slipped at 0.32 gigapascals, as compared to the nylon, polypropylene and polyesters, which failed at higher values, right?
A. Right, but let me just say one thing. There is no standard error given in this thing.
Q. Okay.
A. Whether it's -- 0.32 is different from 0.48, I don't know.
Q. You don't know?
A. No, because unless you provide a standard deviation that's statistically significant, I do not know.
Q. Okay. How about with the knot pull strength in the last column, does he provide any standard deviations for those?
A. No, but you can, because the magnitude difference is three times. It's 1.35 versus 0.42, that's nylon, and that's about three times. So, I'm sure it's higher significantly.
Q. Okay.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation

Defendant.

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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A Again, as far as I know, you got to do the statistical analysis of the whole data.
Q Did you --
A You cannot pick this 27 percent times it goes up and down because if you do it -- more experiments, that 27 percent could be the other -- the other way.
Q It might go up? It might go up to 50 percent?
A Yeah, it could be. Could be. But that's why you take the average and the standard deviation. That's what I didn't do but that I should have done.
Q Okay. Can you explain why -- look at -- if you go down the left-hand side of the page you see the entry of 22 September '05?
A 206874?
Q 2687 to 22 September '05?
A Yeah.
Q The value went from die of 16.61 to measure of 15.05.
A Right.
Q Can you explain that?
A No. The same -- same my explanation as before, I explained to you before.
Q Did anyone tell you about intermediate

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stage of data from Pearsalls?
A I don't remember.
Q Okay. Did you ask for the intermediate stage data?
MR. TAMBURO: Objection, assumes facts.
A I did not.
BY MR. BONELLA:
Q Okay. Do you know what the difference between the intermediate stage and the measure stage is?
A No, I do not.
Q Okay. Did you -- in relying on Exhibit 25 did you consider any error analysis of your data?
A No, I did not.
Q Okay. In the average at the end that you saw of Exhibit 25 --
A Uh-huh.
Q -- 14.39 to 14.84 --
A Right.
Q -- is that a statistically significant difference?
A I cannot guess, but I did not do the statistical calculations. I cannot give you the answer.
Q Okay. The next exhibit to your report is

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Exhibit 26.
A Yes.
Q It says properties of PET.
A Yes.
Q And the next -- the third page is nylon 66 properties?
A Page 3?
Q Right.
A Nylon 66.
Q Right, okay. Under the PET it says it's unfilled, and under the nylon 66 it's molding compound.
A That's correct.
Q Okay. These aren't fiber properties, right?
MR. TAMBURO: Objection, assumes facts and it's vague.
A I'm not sure.
BY MR. BONELLA:
Q You're not sure?
A No.
Q In relying on -- in this case to determine properties for PET and -- well, is there a difference between molding compound properties and fiber properties --

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MR. TAMBURO: Objection, vague.
BY MR. BONELLA:
Q -- for nylon 66?
A The -- it can be.
Q Okay.
A But I relied on the suture properties, because that's really the way -- the final product.
Q Okay.
A But fibers, it -- normally, they're stronger than the molding.
Q Okay. Did you rely on -- well, how about unfilled PET? Is that the same as fiber PET?
MR. TAMBURO: Objection. Objection, vague.
A Probably not. It's probably molding also.
BY MR. BONELLA:
Q Okay. I'd like to ask you about a couple documents. I'd like to show you a few Mitek exhibits. 320. Can we put that back together?
A Yeah, okay.
Q Here, why don't you put that back together?
A Okay. Yeah, no, this -- I was -- I was worried about that. Okay, thank you.
Q Ever see this document before?

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suture B with suture B were subtle -- well, let me back up. Did you -- have you been shown Dr. Burks' deposition transcript?
A No.
Q No? Would you like to see it?
A No.
Q Why not?
A Because that's not relevant in my report here.
Q It's not relevant to your opinions?
A I mean right now, what I'm going right through.
Q Is Dr. Burks' deposition transcript relevant to your opinions?
A Based on the -- I was -- I was informed and, as I reported here, that's all I -- I can do right now.
Q Okay. The question is a yes-or-no question. Is Dr. Burks' deposition transcript relevant to your opinions?
MR. TAMBURO: Objection, calls for a legal conclusion.
A No. I rely on the expert report.
BY MR. BONELLA:
Q Okay. Would you -- if he said in his

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deposition that the differences between suture A and suture B were subtle, is that information you'd like to consider in forming your opinions?
A No.
MR. TAMBURO: Objection.
BY MR. BONELLA:
Q Why not?
MR. TAMBURO: Mischaracterizes the testimony, vague question, and calls for legal conclusion.
BY MR. BONELLA:
Q Why not?
A Again, I go by his expert report that he saw the difference. That's the only thing that I can go by so I cannot answer your question, no.
Q If he -- if he described the differences between suture A and suture B as subtle and it was even with gloves off, is that something you'd like to know?
MR. TAMBURO: Objection, vague.
A No.
MR. TAMBURO: Mis -- give me a chance to object.
THE WITNESS: Okay. Sorry.
MR. TAMBURO: Okay? Objection, vague, and

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mischaracterizes the testimony, incomplete hypothetical.
BY MR. BONELLA:
Q So you don't want to know what his testimony was about the tests?
MR. TAMBURO: Objection, mischaracterized the witnesses testimony.
A Correct. I don't want to know.
BY MR. BONELLA:
Q And you don't want to know what Dr. Burks testified about how he actually did the test in his deposition?
A No.
Q And do you know want to know how Dr. Burks described the results that he obtained from the test in the deposition?
A No.
Q "No," meaning you don't want to know?
A That's correct.
MR. BONELLA: Let's take a quick break.
THE VIDEOGRAPHER: Now going off the video record at 11:04 a.m.
(A recess was taken from 11:04 a.m. through 11:18 a.m.)
THE VIDEOGRAPHER: We're now back on the

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video record. The time is 11:18 a.m. and this is the start of tape two, volume two in the continuing deposition of Debi Prasad Mukherjee.
(Exhibit No. 364 was marked.)
(Exhibit No. 365 was marked.)
BY MR. BONELLA:
Q Dr. Mukherjee, we've marked what counsel has produced for inspection here at the deposition as DePuy Mitek Exhibit 364 is a suture that -- in a bag that's labeled as uncoated, and Exhibit 365 is a suture in a bag labeled as coated. Do you see those?
A Yes.
Q Are those the sutures that you performed a drape test on?
A Yes.
Q Now, the drape test that you performed, is there any literature that describes drape tests?
A No, this is just a very subjective test. And I just wanted to get a feel for that. That's why I did. It's not scientific.
Q Is the drape test that you performed, is that subject to peer review?
A No, it isn't.
Q No? Okay. Can you show me -- well, let me back up. When you were given the samples to

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perform the drape test, do you know where they came from?
MR. TAMBURO: Objection, vague.
A For sure, I didn't know, but I had to depend on the counsel where it came from.
BY MR. BONELLA:
Q Well, what did you think? Where do you think they came from?
A I don't know.
Q Okay. Did Dr. Gitis send them to you?
A No.
Q Who gave them to you? Counsel?
A Yes.
Q Where did you perform the drape test?
A It was actually in a hotel in Chicago.
Q Okay.
A I was in a meeting.
Q Who was present?
A Sal was there, Sal, Mr. Tamburo.
Q Anybody else present?
A No.
Q How -- when you were given the samples, were they given to you on spools, or how were they given to you?
A Just like this.

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Q In the bags?
A Not -- I didn't know which one is which.
Q You didn't?
A No.
Q Okay. Doesn't say that in your report, that you didn't know which one was which.
A Before the test, I did not know which one is which.
Q You didn't?
A No.
Q Okay.
A If I -- after the test --
Q Okay.
A -- and I was just curious to know what we found.
Q Okay. Now, the samples that you were given, do you know, are these the exact samples that you were given? Were you given any more samples, or just these two?
A That's it.
Q That's it?
Do you know how these samples were handled before they were given to you?
MR. TAMBURO: Objection, vague.
A I do not know.

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BY MR. BONELLA:
Q Can handling sutures affect its handleability properties?
MR. TAMBURO: Objection, vague.
A It can, but nonabsorbables normally don't. Absorbables, yes, because the change in moisture and handling.
BY MR. BONELLA:
Q Even for nonabsorbables, if you handle them a lot. Even for nonabsorbables, if you handle them and bend them won't that change the -- can't that change the properties?
MR. TAMBURO: Objection, assumes facts and is vague.
A It's possible, but very minimum.
BY MR. BONELLA:
Q Did you ever hear of functional testing?
A Of?
Q Of sutures.
A Yes.
Q And what -- and what do you understand that to be?
A There is different kind of functional test. It depends on the handling, the surgical use, knot tying, all the other things. There are many

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tests.
Q Okay. Have you ever done -- have you ever seen any test results from Dr. Steckel to the difference between sutures that were handled, sutures that were not handled?
A I probably have, but I don't remember.
Q Okay. Did -- have you ever -- did you consider -- in your analysis, did you ask what the history of the Exhibits 364 and 365 sutures were, how they were handled before you got them?
MR. TAMBURO: Objection, vague.
A No, I didn't. This is just a curiosity for my sake. That's what I did, so I was not -- it was not a scientific, just done -- I just wanted to know, because I had suture experience, just to see what it looked like.
BY MR. BONELLA:
Q Could you --
A Go ahead.
Q Could you tell by feeling the sutures which was coated and which was uncoated?
MR. TAMBURO: Objection.
BY MR. BONELLA:
Q Or is it by the drape test that you performed that you thought one was coated and one was

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uncoated?
MR. TAMBURO: Objection, vague and compound.
A I don't remember whether I felt it. I may or may not.
BY MR. BONELLA:
Q Okay. Do you have experience enough that you can tell differences between sutures based on feel, whether they're coated or uncoated?
A I used to, but now it's a little rusty now.
Q Rusty now?
A It was many years ago.
Q Okay. Can you show me with the exhibits how you performed the drape test?
A I didn't understand.
Q Can you show me the drape test that you performed with Exhibits 364 and 365?
A Oh, oh, yes, yes. You want me to show for each one of those samples?
Q Yes, but let me back up before you do that. Did you do at a drape test on any other samples besides Exhibits 364 and 365?
MR. TAMBURO: Objection, vague.
A Not in relation to this suture but we

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always did when I was developing sutures.
BY MR. BONELLA:
Q All right.
A Not in this context, no.
Q Let me ask a better question. Did you do a drape test of any other FiberWire or TigerWire samples in forming your opinions?
A No.
Q No?
A Only these samples.
Q You didn't do a drape test of TigerWire samples?
A The only thing I did not remember at the academy was that I saw a TigerWire suture with Mr. -- what's his name? Bernard?
Q Benovitz.
A Benovitz. I don't remember that.
Q You saw a TigerWire suture, you said?
A Yeah, it was shown there in the -- the -- the booth.
Q But you didn't do a drape test --
A No.
Q -- of the TigerWire?
Did Mr. Tamburo give you TigerWire samples to do a drape test?

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A No.
Q Did you do a drape test of TigerWire while Mr. Tamburo was present?
A No, no. TigerWire, I wouldn't have done anything.
Q Okay. Can you show me then the drape test that you did with Exhibits 364 and 365?
A I'll do the best I can.
Q Okay.
A Remember, this is not a scientific test.
Q Okay.
A It's a -- very subjective. It's my curiosity.
Q Okay.
A This is what I did.
Q Now you're using Exhibit 364?
A I don't know.
Q That's the suture that was out of the Exhibit 364 bag.
A 364, yeah.
Q And you put it over your finger?
A Yeah.
Q Okay.
A And I just looked at two things, you know, how far -- how much this conform. I let it hang like

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that and see how much is conformed to my finger.
Q Okay.
A And, you know, I also look at this part, whether it's really conforming to this side of the finger.
Q Okay.
A Again, this is very subjective, scientific -- not a scientific --
Q Okay.
A -- test.
Q Now, if you pull the suture down on this side --
A Pull this one?
Q Yep, just pull this one down a little bit. Doesn't it change how much --
A No.
Q -- it conforms?
A I didn't -- I didn't want to handle too much, but --
Q Does it --
A -- I didn't see any -- doesn't conform. It's still -- the distance is still --
Q Sure.
A -- considerable.
Q And --

MITEK EXHIBIT 26

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

comparison to the second fiber-forming yarns, and I disagree with Dr. Mukherjee's assertion that they are.

14. As another basis for his opinion of substantial differences, Dr. Mukherjee opines that the differences between the claimed "PE" (if PE does not include UHMWPE) and UHMWPE are substantial because the claimed second fiber-forming materials are "added for strength" and UHMWPE is added to increase FiberWire's strength. I understand that the relevant comparison is between PE and UHMWPE, not between the claimed second fiber-forming materials and UHMWPE. Thus, I am not sure why Dr. Mukherjee is comparing the second fiber-forming materials to UHMWPE. Nevertheless, I disagree with his statement that FiberWire's construction is the opposite of what is described in the 446 Patent. The 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. D at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. I at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. D at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. I at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,[1] of the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot.

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[1] I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test (*see, e.g.,* Ex. O). I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Ex. P, Q. Knot holding strength is an indication of knot security. The 446 Patent describes another exemplary knot security test (Ex. D at 6:36-44).

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

BROOKSTEIN EXPERT REPORT
EXHIBIT D

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

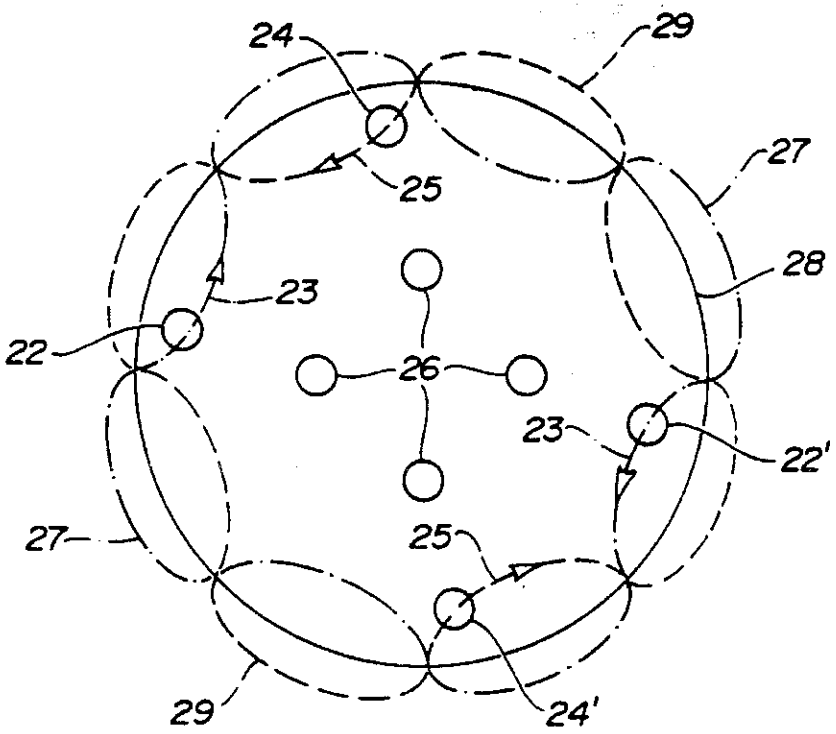
[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1



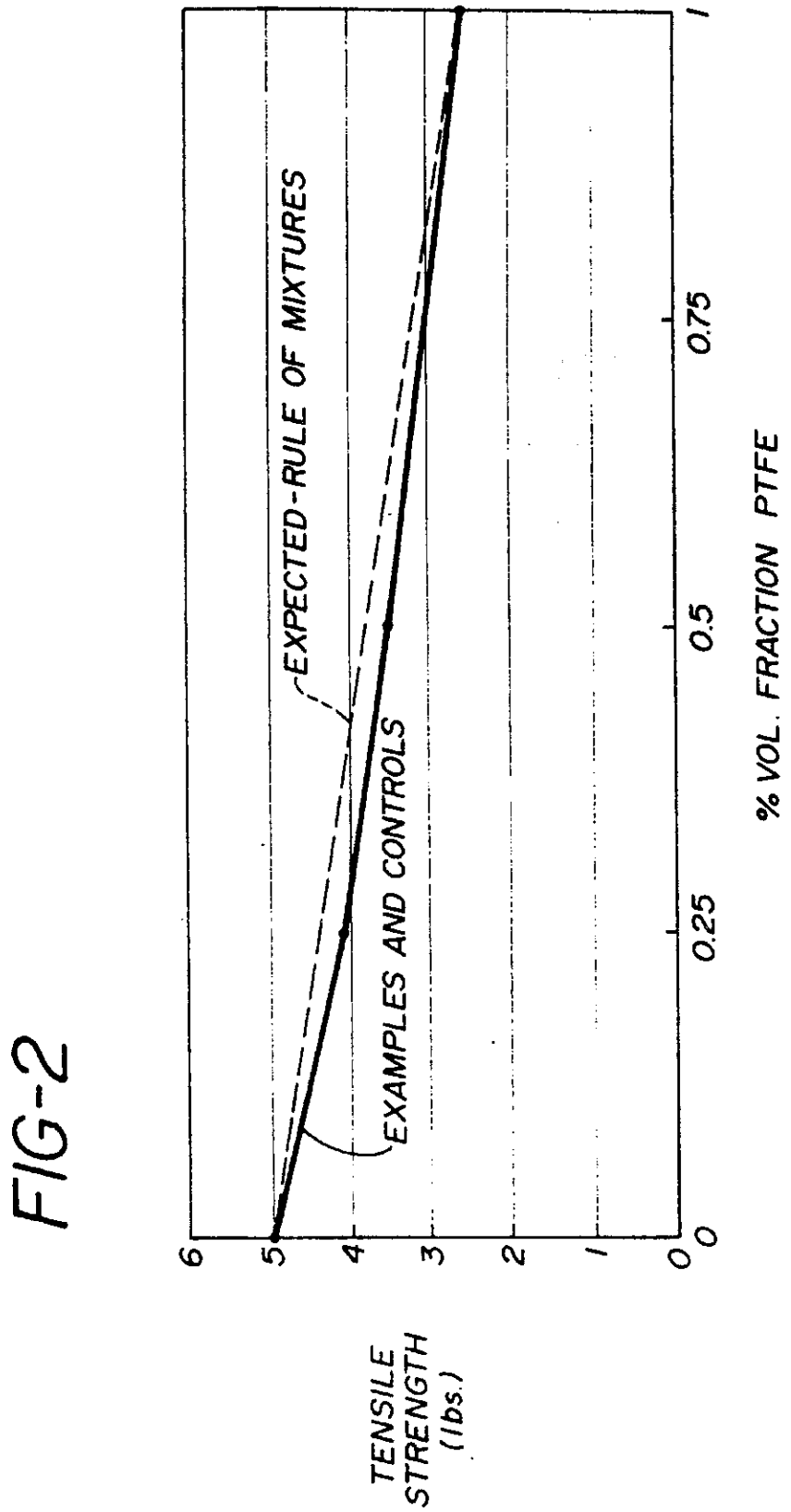
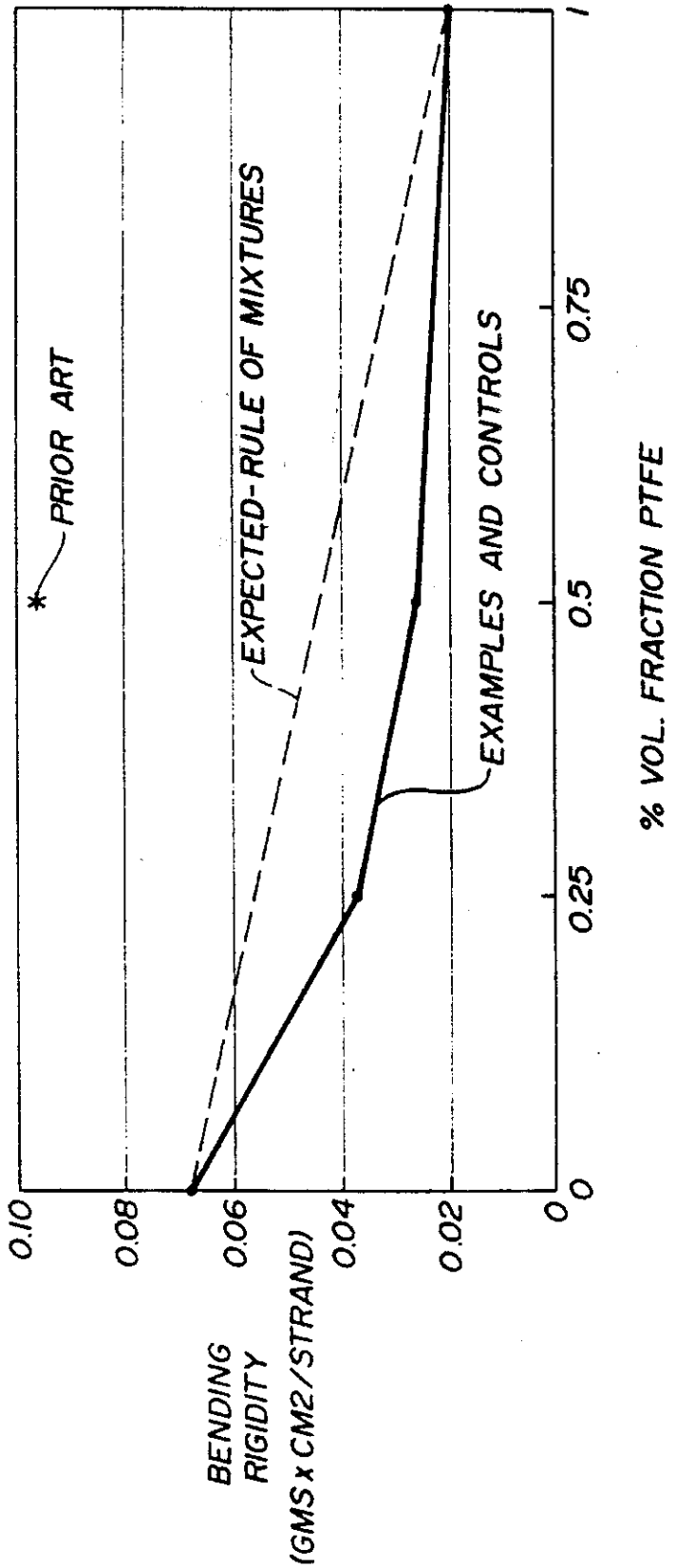

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-2

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

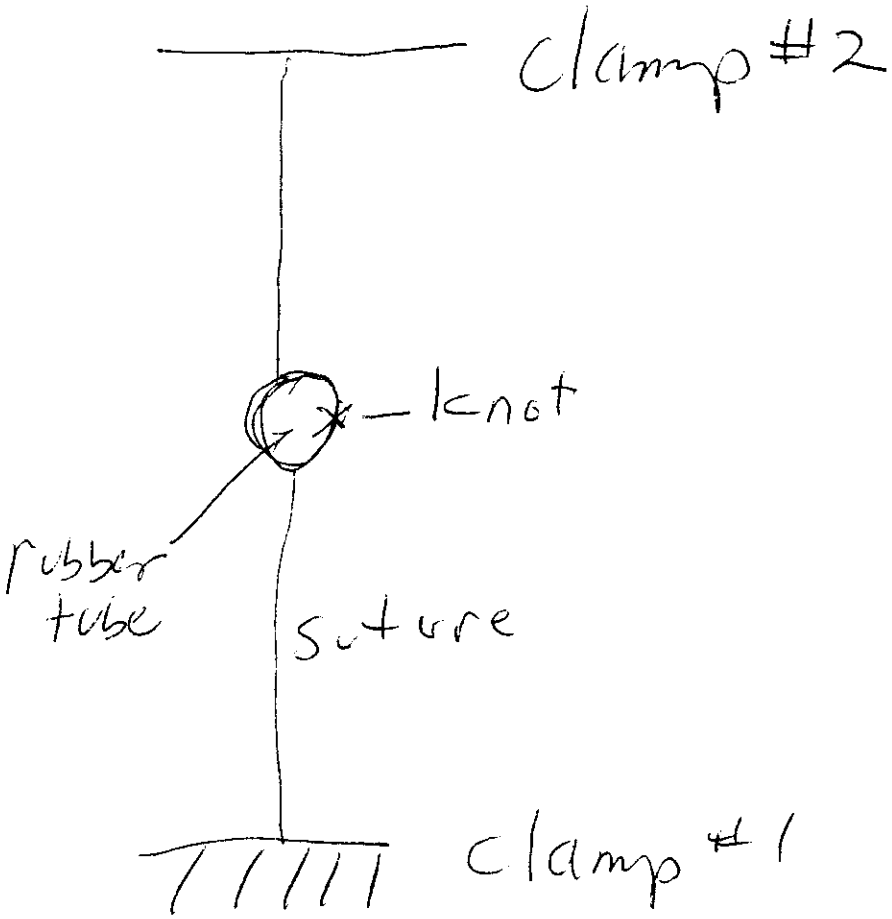
11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

BROOKSTEIN EXPERT REPORT
EXHIBIT O

Knot Strength



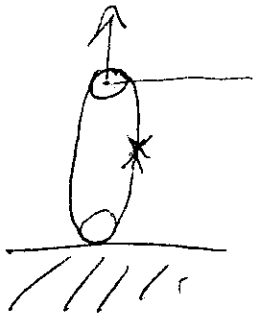
A.H

09/15/05

BROOKSTEIN EXPERT REPORT
EXHIBIT P

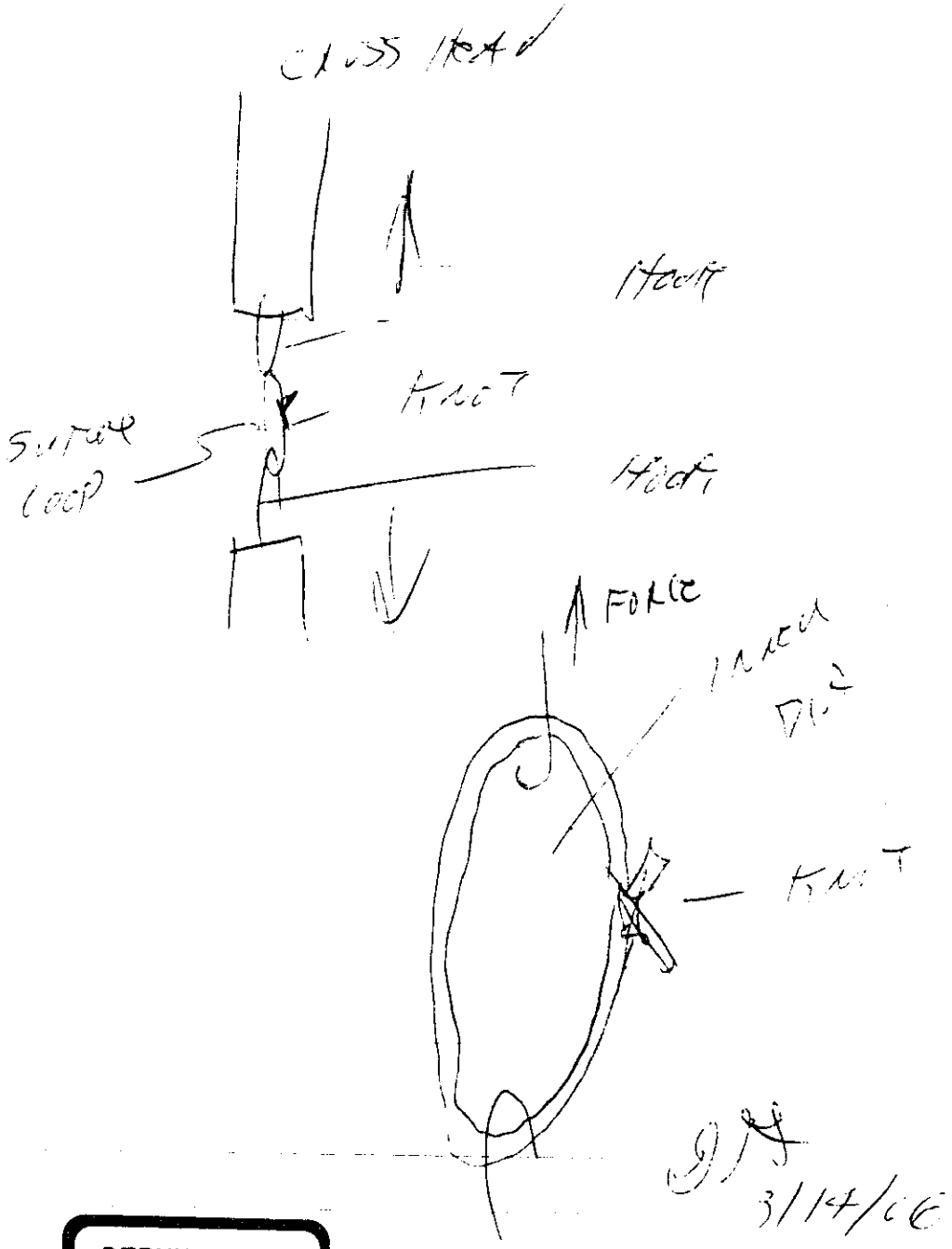
Knot Security

~~Side~~
Front View



A. H. 09/15/05

BROOKSTEIN EXPERT REPORT
EXHIBIT Q



DEPUY MITEK
EXHIBIT 421
04cv12457

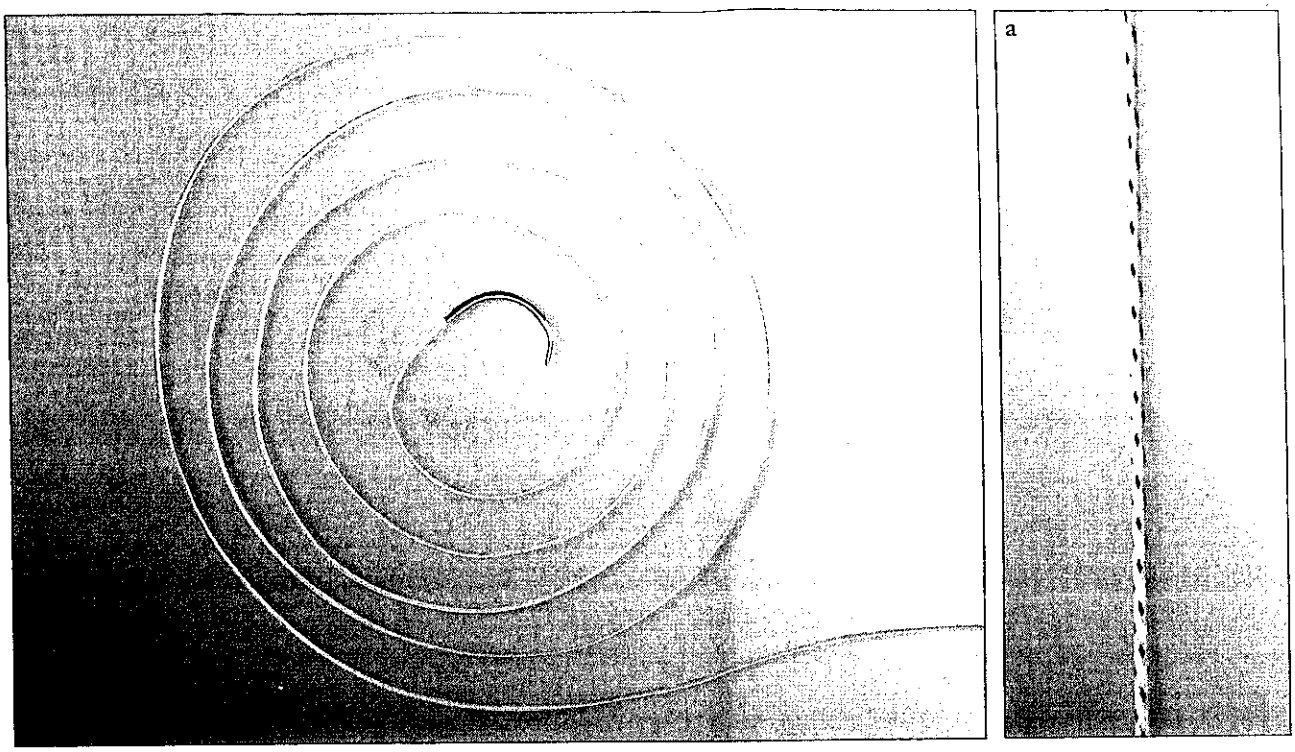
MITEK EXHIBIT 27

PRODUCT CATALOG

2003/2004

Arthrex®

FiberWire™ and TigerWire™



Key Words: **Size #2 with the strength of #5, new composite material technology, abrasion resistant, designed for most orthopaedic reconstruction procedures**

FiberWire is a new generation of nonabsorbable suture with a solid, long chain polyethylene core and a woven polyester jacket. It is the ideal suture for most orthopaedic procedures such as rotator cuff repair, Achilles tendon repair, patellar and quadriceps tendon repair, ACL/PCL, hip, shoulder, hand and foot reconstruction procedures, total joint closure, and in conjunction with suture anchors.

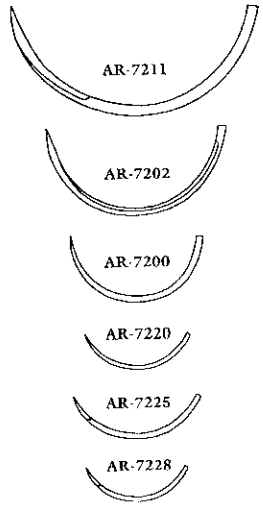
#2 TigerWire, a white suture with black spiral markings, was created specifically for arthroscopic surgeons that require superior suture visibility, easier arthroscopic orientation and motion determination.

All sizes of FiberWire have greater strength than polyester suture with the same diameter, with smoother feel and tie ability. Cyclic loading of #2 FiberWire resulted in 1,000,000 cycles without failure compared to 160,000 cycles of standard #2 polyester to failure.

All FiberWire and TigerWire are sterile.

#2 FiberWire, 38 inches w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12	AR-7200
#2 FiberWire, 38 inches, 2 strands (1 blue, 1 white/black), qty. 12	AR-7201
#2 FiberWire, 38 inches w/Reverse Cutting Needle, 36.6 mm 1/2 circle, qty. 12	AR-7202
#2 TigerWire, 38 inches, white/black, qty. 12 (a)	AR-7203
#5 FiberWire, 38 inches, qty. 12	AR-7210
#5 FiberWire, 38 inches w/Conventional Cutting Needle, 48 mm 1/2 circle, qty. 12	AR-7211
2-0 FiberWire, 18 inches w/Tapered Needle, 17.9 mm 3/8 circle, qty. 12	AR-7220
2-0 FiberWire, 38 inches, qty. 12	AR-7221
3-0 FiberWire, 18 inches w/Diamond Point Needle, 26.2 mm 3/8 circle, qty. 12	AR-7225
4-0 FiberWire, 18 inches w/ Diamond Point Needle, 18.7 mm 3/8 circle, qty. 12	AR-7228

PATENTS PENDING



MITEK EXHIBIT 28

LEXSEE 1998 US DIST LEXIS 23054

BASF CORPORATION, Plaintiff, v. EASTMAN CHEMICAL CO., Defendant.

Civil Action No. 95-746-RRM

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1998 U.S. Dist. LEXIS 23054; 56 U.S.P.Q.2D (BNA) 1396

March 24, 1998, Decided

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent holder commenced a patent infringement action against defendant competitor. The competitor counterclaimed for a declaratory judgment of noninfringement and invalidity. The court held a non-jury trial on the issues of infringement, willful infringement, and invalidity.

OVERVIEW: The holder asserted that a process used by the competitor to prepare 2,5-dihydrofuran from the chemical epoxy 1 butene infringed a claim made by its patent. The court found in favor of the competitor. The scope of a patent claim was defined by its language. While a court was permitted to consider the prosecution history and the like in its interpretation, reliance on such extrinsic evidence was improper when the language unambiguously defined a claim's scope. Given those considerations, the holder's claim excluded the addition of a solubilizer, as that component would alter its basic and novel characteristics. Furthermore, the claim only provided that the catalysis had to occur in a liquid phase and did not exclude gas feed processes. Therefore, the competitor's process did not infringe the holder's claim. Moreover, that claim was invalid because every one of its elements had been reduced prior to the priority date of the holder's application. In that regard, the delay between that reduction and the competitor's patent application was not evidence of abandonment or concealment because scientists were entitled to a reasonable amount of time in which to refine their invention.

OUTCOME: The court found that the competitor had not infringed one of the claims contained in the holder's patent. The court further held that claim was invalid on the grounds of priority of invention and that the competitor had not abandoned, suppressed, or concealed the invalidating prior reductions to practice.

LexisNexis(R) Headnotes

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN1] Before a court can decide issues such as infringement, willful infringement, and invalidity, the court must first construe the language of a claim made by a patent.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN2] A court construes claims from the vantage point of a person of ordinary skill in the art at the time of the invention. However, the court may interpret a term in a patent claim to have a meaning other than the one a person of ordinary skill in the art would give it if it is apparent from the patent and the prosecution history that the inventor intended a different meaning.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN3] In construing a claim, a court looks first to the intrinsic evidence of record, namely, the language of the claim, the specification, and the prosecution history. The claim language itself defines the scope of the claim, and a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language. Expert testimony may be considered if needed to assist the court in understanding the meaning or scope of technical terms in a claim. However, reliance on any extrinsic evidence is improper where the claims, specification, and file history unambiguously define the scope of the claim.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN4] Although the Court of Appeals for the Federal Circuit has held that claims should be read in light of the specification, that court has repeatedly cautioned against limiting the scope of a claim to the preferred embodiment or specific examples disclosed in the specification.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN5] The Court of Appeals for the Federal Circuit has stated that the limited phrase "consisting essentially of" does not exclude the addition of another ingredient which does not materially affect the characteristics of the invention. The Federal Circuit has also stated that "consists essentially of" does close the claims to other ingredients that do alter the basic and novel characteristics of the invention.

International Trade Law > Imports & Exports > General Overview
Patent Law > Infringement Actions > Infringing Acts > Sale
Patent Law > Infringement Actions > Infringing Acts > Use

[HN6] Section 271(a) of the Patent Act states that whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent. *35 U.S.C.S. § 271*(a).

Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Date of Invention & Priority > Conception Date
Patent Law > Date of Invention & Priority > Reduction to Practice

[HN7] Section 102(g) of the Patent Act, *35 U.S.C.S. § 102*(g), provides that a person is entitled to a patent unless before the application's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Evidence > Procedural Considerations > Burdens of Proof > Clear & Convincing Proof
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption

[HN8] A claim contained in a patent is presumed to be valid. *35 U.S.C.S. § 282*. The challenging party bears the burden of proving invalidity by clear and convincing evidence. Clear and convincing evidence is shown when the trier of fact has an abiding conviction that the truth of the factual contentions is highly probable.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Reduction to Practice

[HN9] To show prior reduction to practice, a party must show that its work meets every element of the claimed invention before the priority date of a patent application.

Patent Law > Anticipation & Novelty > General Overview

[HN10] There cannot be a reduction to practice of the invention without a physical embodiment which includes all limitations of the claim.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Statutory Bars > Abandonment & Forfeiture Bar > General Overview

[HN11] In order to show that it did not abandon, suppress, or conceal experiments within the scope of a claim, a party must show that it disclosed the process of the claim in a manner that would bring the benefit of the knowledge of the invention to the public, and that it did not unreasonably delay this disclosure.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Statutory Bars > Abandonment & Forfeiture Bar > General Overview

[HN12] It is necessary to consider the nature and extent of activity during the period between reduction to practice and the filing of the patent application.

Patent Law > Anticipation & Novelty > General Overview

Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > Priority
[HN13] The Court of Appeals for the Federal Circuit has stated that when determining whether an inventor has abandoned, suppressed, or concealed an invention, a period of delay between completion of the invention and subsequent public disclosure is not always of legal significance.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Statutory Bars > Abandonment & Forfeiture Bar > General Overview
[HN14] Mere delay, without more, is insufficient to demonstrate abandonment, suppression, or concealment.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Ownership > Conveyances > Assignments
[HN15] Scientists should be given a reasonable amount of time to refine their invention. A reasonable amount of time should be allowed for completion of the research project on the whole series of new compounds, a further reasonable period should then be allowed for drafting and filing the patent application(s) thereon, without subjecting the prior inventor or his assignee to the risk of forfeiture of valuable patent rights due to alleged concealment or suppression of the invention.

COUNSEL: [*1] For plaintiff: Josy W. Ingersoll, Esquire, Young, Conaway, Stargatt & Taylor, Wilmington, Delaware.

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For defendant: William J. Marsden, Jr., Esquire, Joanne Ceballos, Esquire, Michael S. McGinniss, Esquire, Potter, Anderson & Corroon, Wilmington, Delaware.

For defendant: Ralph A. Mittleberger, Esquire, Barry E. Bretschneider, Esquire, Howard Susser, Esquire, William R. Johnson, Esquire, Fish & Richardson, P.C., Washington, D.C.

For defendant: Frank P. Porcelli, Esquire, Ronald E. Myrick, Esquire, Fish & Richardson, P.C., Boston, Massachusetts.

For defendant: R. Danny Huntington, Esquire, B. Jefferson Boggs, Jr., Esquire, Nhat D. Phan, Esquire, Todd R. Walters, Esquire, Burns, Doane, Swecker & Mathis, LLP, Alexandria, Virginia.

JUDGES: Roderick McKelvie, District Judge.

OPINIONBY: Roderick McKelvie

OPINION:

REVISED MEMORANDUM OPINION

Dated: March 24, 1998

McKELVIE, District Judge

This is a patent case. Plaintiff BASF Corporation ("BASF") owns U.S. Patent No. *5,034,545* ("the *'545* [*2] patent"), which claims a process for the preparation of the chemical 2,5-dihydrofuran ("DHF") from the chemical epoxy 1 butene ("EpB"). BASF alleges that defendant Eastman Chemical Co.'s ("Eastman") process for the commercial production of DHF infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing. Eastman has denied infringement, asserted the affirmative defense of invalidity on the grounds of priority of invention, and counterclaimed for a declaratory judgment of noninfringement and invalidity.

From October 14 to October 22, 1997, the court held a non-jury trial on the issues of infringement, willful infringement, and invalidity. At trial, BASF alleged that the process Eastman is using at its Longview, Texas plant to commercially prepare DHF infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing claim 6. Eastman argues that it is not infringing claim 6 of the *'545* patent, as the process it uses in Longview is not covered by claim 6. Furthermore, Eastman argues that claim 6 of the *'545* patent is invalid on the grounds of priority of invention because experiments done by Eastman scientists before BASF filed the *'545* patent application [*3] constitute prior reductions to practice of claim 6, and Eastman scientists disclosed the results of these experiments in a patent application filed in March 1990.

The following is the court's decision on these issues.

I. FACTUAL AND PROCEDURAL BACKGROUND

The court draws the following facts from the pretrial order and from the evidence presented at the trial.

A. The Technology

The technology at issue in this matter involves the preparation of DHF from EpB. DHF is a solvent and starting material that can be used to make products such as Spandex and other products in the plastics industry. EpB is a compound with negligible commercial value. Through a chemical process known as catalysis, EpB can be transformed to DHF. Catalysis is the action of a catalyst, a substance which alters the rate of a chemical reaction without being depleted in the process. The catalyst creates a reaction that rearranges the manner in which the atoms that make up EpB are bound together, without altering the number of atoms. Because EpB can create end products other than DHF, the catalyst used for this rearrangement is critical to the process.

Scientists have explored many different methods [*4] for the catalytic rearrangement of EpB to DHF. In January 1976, the Patent and Trademark Office ("PTO") issued U.S. Patent No. *3,932,468* ("the Kurkov patent") to the Chevron Research Company. The Kurkov patent discloses a process for producing DHF using a catalyst of "hydrogen iodide or bromide and a homogenous transition metal compound in an organic solvent." In December 1976, the PTO issued U.S. Patent No. *3,996,248* ("the Wall patent") to Chevron. The Wall patent discloses a process for producing DHF using a catalyst of "hydrogen halide selected from the group consisting of hydrogen iodide or bromide and a Lewis acid."

Both processes claimed by the Kurkov and the Wall patents are solvent-based. One significant disadvantage of solvent-based processes is the need to remove the DHF from the reaction mixture through a distillation process. Distillation constitutes a separate step of the recovery process, and renders the process less efficient and less economical. Thus, during the 1980's, scientists at BASF and Eastman sought to create alternative catalyst systems for converting EpB to DHF without the disadvantages associated with the use of large amounts of solvent. The dates on which [*5] these scientists discovered and reduced to practice certain catalyst systems is integral to the dispute between BASF and Eastman.

B. The *'545* Patent

On May 23, 1990, BASF Aktiengesellschaft ("BASF AG"), a German corporation, filed a patent application with the PTO, which matured into the *'545* patent. The PTO issued the *'545* patent on July 23, 1991. Martin Fischer, the named inventor, assigned the *'545* patent to BASF AG, which subsequently assigned it to BASF.

In August 1989, approximately one year before filing the *'545* patent application, BASF AG filed an application in Germany. The *'545* patent application claimed priority to the German application, which means that the *'545* patent application received the benefit of the earlier filing date of August 8, 1989. See *35 U.S.C. § 119* (1997).

The *'545* patent teaches that the catalytic rearrangement of EpB can occur using a three part catalyst system at a temperature between 60 [degrees] and 200 [degrees] Celcius. This catalyst system includes component A, which "is a halide of an alkali metal or alkaline earth metal or an onium halide." Component A is the active ingredient that starts the reaction [*6] with the EpB. Component B dissolves component A so that it can mix with the liquid solution during catalysis. Component B "is an organic solubilizer for component A." Component C "is a Lewis acid or elemental iodine."

The original application for the *'545* patent included five claims. Claim 1 of the patent claimed a process for the preparation of DHF from EpB which

> comprises the rearrangement being catalyzed by a system which contains components A, B and C, at from 60 [degrees] to 200 [degrees] C., where
>
> A is a halide of an alkali metal or alkaline earth metal or an onium halide,
>
> B is an organic solubilizer for component A, and
>
> C is a Lewis acid or elemental iodine, with the proviso that at least one of components A or C is an iodide.

Claims 2 to 5 depended from claim 1.

The original application for the *'545* patent included a discussion of the amount of component B necessary to dissolve component A. As noted in the patent application, "the amount of solubilizer B required to solubilize component A greatly depends on the particular substance." The patent application also noted that onium halides, which may be used as component A, have a "certain intrinsic solubility [*7] in the organic reaction medium." Accordingly, the solubility of the "onium halides with four alkyl or aryl substituents may be so great in the reaction medium that virtually no addition of solubilizer B is necessary." This language, which constituted part of the original application filed with the PTO, is included at column 4, lines 36 to 58 of the *'545* patent.

On November 6, 1990, during the prosecution of the *'545* patent, the patent examiner relied on the language in the patent specification, and noted that solubilizer may

not be necessary when certain halides are used as component A. The examiner noted that "this 'no solubilizer' embodiment is intended to be covered by the claims." Thus, the examiner suggested what eventually became claim 6 of the *'545* patent.

On January 24, 1991, BASF AG added amended claim 6 to the *'545* patent. Claim 6 limits component A to onium halides that are "substantially soluble in the reaction medium," Claim 6 claims a process for the preparation of DHF from EpB which

> consists essentially of the rearrangement being catalyzed by a system which contains components A and C from 60 [degrees] to 200 [degrees] C where A is an onium halide, which [*8] is substantially soluble in the reaction medium, and C is a Lewis acid or elemental iodine with the proviso that at least one of the components A or C is an iodide.

C. Eastman's Catalytic Rearrangement

In the 1980's, Eastman scientists were also experimenting with different catalyst systems for converting EpB to DHF. In particular, three scientists focused their studies on the catalytic rearrangement of EpB Dr. Stephen Falling, Dr. John Monnier, and Dr. Howard Low.

In January 1987, Monnier notified Dr. Windell Watkins that he had discovered a process for cheaply manufacturing EpB from butadiene. Watkins invited Monnier to come from Eastman's Rochester, New York plant, to its Longview, Texas plant to give a seminar on his research on converting butadiene to EpB. On February 24, 1987, Watkins wrote a memo to Monnier and Steve Godleski, another research scientist at Rochester, indicating an interest in working with scientists at the Rochester plant to "develop a process for epoxy-butene and . . . to develop some other chemicals that are easily derived from EpB."

As a result of Watkins' memo, in December 1987, Eastman scientists held a meeting at the Rochester plant to discuss [*9] whether to convene a team to develop a process for preparing EpB and EpB derivatives. Following the meeting, the scientists created an EpB team comprised of, among others, Watkins, Godleski, Monnier, Low, and Falling. Watkins headed the EpB team. Although the scientists did not all work at the same Eastman plant, they kept one another informed of the results of their experiments. For example, beginning in the summer of 1988 and continuing through the end of 1990, Falling circulated monthly reports to other members of the EpB team documenting the progress of his experiments.

1. Falling's, Monnier's, and Low's experiments

In June 1988, Falling began to explore different processes for catalytically rearranging EpB to DHF. Falling's experiments always included EpB in liquid form. At trial, Falling testified about some of the experiments he conducted.

On June 9, 1988, Falling catalytically rearranged EpB to DHF by mixing a Lewis Acid (zinc chloride), an onium halide (tetrabutylammonium iodide), a solvent (toluene), and EpB at 100 [degrees] C, resulting in 4.4% DHF. On June 15, 1988, Falling mixed a Lewis acid (zinc chloride), an onium halide (tetrabutylammonium iodide), a solvent [*10] (toluene), and EpB at 150 [degrees] C. The end product was 21.2% DHF.

On June 28, 1988, Falling attempted an experiment with a different Lewis acid (zinc iodide), an onium halide (tetrabutylammonium iodide), a solvent (toluene) and EpB at 150 [degrees] C. Two days later, Falling ran a similar experiment, using dioxane instead of toluene. The result was 92.3% DHF. At trial, Falling noted that "this experiment was very successful. It showed even greater amounts of DHF" than the prior experiments.

On July 6, 1988, Falling conducted a "neat" experiment. An experiment is neat when neither solubilizer nor solvent is added. Falling obtained DHF by mixing EpB with only a Lewis acid (zinc iodide) and an onium halide (tetrabutylammonium iodide) at 66 [degrees] to 70 [degrees] C. This catalyst combination produced 71.2% DHF. Two days later, on July 8, 1988, in a monthly report from Falling to Watkins and other members of the EpB team, Falling reported that the "best catalyst system studied thus far is [zinc iodide / tetrabutylammonium iodide,]" which included the neat experiment, and the earlier experiment with dioxane. Falling also reported that "runs without solvent or in dioxane [*11] have been the most encouraging with regard to DHF/crotonaldehyde ratios. These runs appear to be clean and go to complete conversion of EpB."

Falling continued to experiment with various Lewis acids, onium halides, and solvents to obtain DHF. Falling also conducted more neat experiments. On July 18, 1988, Falling conducted a neat experiment, using tetrabutyltin iodide and tetrabutylphosphonium iodide at 66 [degrees] to 70 [degrees] C. Only trace amounts of DHF were detected, and Falling discarded the experiment. Falling concluded that "some reaction had occurred" and that "these conditions were not optimum for this particular reaction." On July 27, 1988, Falling conducted another neat experiment, using magnesium iodide and tetrabutylammonium iodide at 66 [degrees] to 70 [degrees] C,

resulting in a trace amount of DHF. Falling discarded this experiment. Falling testified at trial that 66 [degrees] to 70 [degrees] C is "just too low a temperature to achieve very much reaction," and that if he had run the experiment at a higher temperature, he predicted that he "would obtain much more reaction."

On October 3, 1988, Falling successfully produced 71.7% DHF when he mixed a [*12] Lewis acid (tributyltin iodide), an onium halide (tetrabutylphosphonium iodide), and a solvent (toluene), at 150 [degrees] C.

In most of the above experiments, except the neat experiments, Falling used a solvent. At trial, Falling testified that he used toluene as the solvent because EpB was in short supply and he had to conserve it, and "toluene had the purpose of diluting the mixture so as to cut down polymerization chemistry and to favor the rearrangement reaction."

Falling continued to experiment with various catalyst combinations throughout 1989 and 1990, circulating monthly reports documenting his progress. In an August 1, 1989 memo sent to members of the EpB team Falling wrote that "the screening of catalyst systems for the homogenous rearrangement of EpB to 2,5-DHF is still in progress."

At the same time that Falling worked on developing a process for converting EpB to DHF, Monnier and Low were also experimenting with various catalysts. Because of the equipment capabilities at the Rochester plant, all of their experiments were gas feed, which meant that they used EpB in gas form.

Monnier and Low testified at trial that they initially used metallic iodides as a catalyst. [*13] However, Watkins thought that Falling's use of an onium halide and a Lewis acid as a catalyst constituted a major breakthrough for converting EpB to DHF. Thus, from November 1988, to January 1990, Monnier and Low conducted several experiments using this catalyst to rearrange EpB to DHF. The experiments were run at approximately 110 [degrees] to 185 [degrees] C. Low testified that the conversion to DHF was "pretty successful" when they used onium halides and a Lewis acid.

2. The patent applications

On March 8, 1990, Eastman filed U.S. Patent Application Serial No. 07/490,208 ("the '208 application") which claimed a process for the catalytic rearrangement of EpB to DHF by mixing a Lewis acid and an onium halide. This process used neither a solubilizer nor a solvent at a temperature range of 60 [degrees] to 225 [degrees]. The '208 application was mainly based on the gas feed, liquid phase catalyst work done by Monnier and Low. Although the '208 application generally covered Falling's work, it did not include any working examples from Falling's notebooks, and Falling was not listed as an inventor on the application. Eastman filed the '208 application approximately two and [*14] a half months before BASF filed the *'545* application.

On July 23, 1990, Falling and Patricia Lopez-Maldonado, a scientist working with Falling since July 1989, completed an invention report and submitted it to Eastman's patent department. The report stated that "[a] catalytic process has been discovered with the rearrangement of vinyl epoxides to 2,5-dihydrofurans in good yield and selectivity. The process comprises contacting a vinyl epoxide [EpB] with a catalytic amount of an organotin or organoantimony compound and an organic-soluble iodide or bromide salt in an inert solvent at elevated temperatures." Organotins or organoantimony compounds are Lewis acids.

The report also stated that the "process is an improvement over the prior art in that it does not require the use of corrosive hydrogen halides or expensive tertiary amide solvents." The report stated that "although the rearrangement reaction can be performed in the absence of solvent, the use of an inert organic solvent or diluent is normally preferred for ease of materials handling. The vinyl epoxide rearrangement can be performed in any solvent which is unreactive towards epoxides and the catalysts."

This invention [*15] report became the basis for a December 14, 1990 addendum to the '208 application, a continuation in part ("CIP"). The CIP added to the '208 application working examples of the liquid phase experiments using a catalyst system of an onium halide and a Lewis acid that Falling had worked on during the summer of 1988. Because the CIP contained some new subject matter, the new subject matter had its own filing date of December 14, 1990.

Eastman filed the CIP as a new patent application, U.S. Application Serial No. 627,668 ("the '668 application"). The '668 application disclosed a process for converting EpB to DHF using a catalyst of an onium halide and a Lewis acid, and no solubilizer. Eastman eventually abandoned the '208 application in favor of the '668 application. The '668 application matured into U.S. Patent No. *5,082,956* ("the *'956* patent"), which the PTO issued to Eastman on January 21, 1992. Monnier, Godleski, Low, and Gerald W. Phillips, a scientist at the Longview plant, are listed as inventors. The *'956* patent discloses a process for converting EpB to DHF where the "catalyst may comprise a supported catalyst, an unsupported catalyst or a solution of the catalytically-active components [*16] in an inert, organic solvent."

During the early to mid-1990's, Eastman filed other patent applications as Eastman scientists continued experimenting with processes for catalytically rearranging

EpB into DHF. On February 10, 1994, Eastman filed U.S. Application Serial No. 08/194,655 ("the '655 application"), which claims a process for the catalytic rearrangement of EpB to DHF using a catalyst system of an onium halide and a Lewis acid. Falling is listed as the inventor on the '655 application.

The '655 application is a continuation in part of Application Serial No. 07/746,530, which was filed in August 1991, and which is a divisional application of the '668 application. The divisional application is based on the parent application, the '668 application, and it has the same specifications but different claims. The divisional application is entitled to the filing date for the '668 application, December 14, 1990. The '655 application is still pending.

On May 24, 1994, the PTO issued U.S. Patent No. *5,315,019* ("the *'019* patent") to Eastman. Phillips, Falling, Monnier, and Godleski are listed as the inventors. The *'019* patent discloses a "continuous process for the manufacture of [DHF] [*17] by the isomerization of [EpB] in the liquid phase in the presence of a catalyst system comprising an onium iodide compound and a Lewis acid and a process solvent comprising a mixture of the [DHF] product of the process and an oligomer of the [EpB] reactant." Thus, the *'019* patent discloses a process in which the onium halides are intrinsically soluble in the reaction medium, which essentially eliminates the need for added solvent.

At column 2, line 60, to column 3, line 3, the *'019* patent states that the "advantages provided by the continuous process disclosed herein include milder reaction conditions, simplified product separation and the ability to remove and replenish the catalyst system." Additionally, the "use of a mixture of the [DHF] product and an oligomer of the [EpB] reactant as the inert process solvent allows the reaction to be run at temperatures substantially lower than those used in vapor phase processes," and "as a result, the potential for catalyst deactivation or decomposition and by-product formation is decreased."

D. The Interference

On November 3, 1994, the PTO declared an interference between claims 1 to 6 of BASF's *'545* patent and Eastman's pending [*18] '655 application. (Monnier et al. v. Martin Fischer, Interference No. 103,455). The PTO declared the interference for the purpose of determining whether BASF or Eastman first catalytically rearranged EpB to DHF using a catalyst system of an onium halide and a Lewis acid.

On November 29, 1995, Administrative Patent Judge Marc L. Caroff declared unpatentable claims 1 to 5 of the *'545* patent because example 6 of the Wall patent disclosed a process for the preparation of DHF from EpB using a catalyst system that anticipated claims 1 to 5. Judge Caroff also determined that claim 6 of the *'545* patent is directed to the same invention Eastman claims, and that if Eastman's application matures into a patent, claim 6 of the *'545* patent will be declared invalid on the basis of Eastman's priority of invention.

The interference proceedings are still pending.

E. The Longview Process

Eastman is currently working on a method for commercially producing DHF from its plant in Longview, Texas. At Longview, Eastman commences the process of catalytically rearranging EpB to DHF using a specific onium halide, THF (tetrahydrofuran), which is a solubilizer, and a specific Lewis acid, at 70 [degrees] [*19] to 117 [degrees] C. Gerald Butler, a chemical engineer at Eastman, testified at trial about the Longview process.

At start-up, there is a one-to-one ratio of the onium halide to THF. The THF is added to the EpB to help dissolve the onium halide. Within six to twelve hours of adding both products distillation begins, and shortly thereafter a large portion of the THF is removed. The DHF produced soon outweighs the THF, and THF becomes less important to carry out the reaction. Eventually, no THF is left in the system.

When the EpB is added to the mixture of onium halide, THF, and Lewis acid, and DHF is produced, approximately 3% of the EpB is converted to oligomer. Eastman's expert in organic chemistry, Dr. John Swenton, testified at trial that the textbook definition of oligomer is a "substance composed of molecules containing a few of one or more species of atoms or groups of atoms . . . repetitively linked to each other." As the DHF is produced, it is stored separately, and the oligomer is recycled back into the system to convert EpB to DHF. The oligomer is eventually built up to where it constitutes a substantial proportion of the system. The oligomer replaces the solubilizing [*20] function of the THF at start-up and helps keep the onium halide in a liquid state. The oligomer is inherently produced during the reaction. By recycling the oligomer back into the process to act as a solubilizer, the process can be run for months at a time.

F. The Lawsuit

On December 7, 1995, BASF filed a complaint alleging that the Longview process infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing. On January 12, 1996, Eastman filed an answer denying infringement, asserting the affirmative defense of invalidity on the grounds of priority of invention, and counterclaiming for a declaratory judgment of noninfringement and invalidity.

On April 15, 1997, Eastman filed a motion for leave to amend its answer and counterclaim and to add BASF AG as a party. Eastman sought to add several affirmative defenses, including the affirmative defenses of fraud, inequitable conduct, and unclean hands. Eastman also sought to add additional counterclaims, including a counterclaim for unfair competition pursuant to Delaware common law and statutory law, and counterclaims for a declaratory judgment that the *'545* patent is unenforceable because of inequitable conduct, [*21] and that BASF is guilty of unclean hands. On July 31, 1997, the court granted Eastman's motion.

From October 14 to October 22, 1997, the court held a non-jury trial on the issues of infringement, willful infringement, and invalidity. At trial, BASF argued that the "virtually solvent-free process" which Eastman uses at Longview infringes claim 6 of the *'545* patent. Furthermore, BASF argued that Eastman knew about the *'545* patent before it commenced the production of DHF at Longview. Eastman argued that the Longview process does not infringe because of the use of a solubilizer, THF, at start-up, and the continuous use of a solubilizer, recycled oligomer, throughout the process. Furthermore, Eastman argued that Falling's neat experiments and his experiments using toluene as an inert solvent, and the gas feed work of Monnier and Low establish priority of invention. Therefore, Eastman argued that claim 6 of the *'545* patent is invalid. See *35 U.S.C. § 102*(g) (1997). BASF argued that if these experiments establish prior inventorship, claim 6 is not invalid because Eastman abandoned, suppressed, or concealed this work.

On November 24, 1997, the parties stipulated [*22] that resolution of all other issues would be stayed pending the court's decision on infringement, willful infringement, and invalidity.

II. DISCUSSION

[HN1] Before the court can decide the issues of infringement, willful infringement, and invalidity, the court must first construe the language of claim 6 of BASF's *'545* patent.

A. Claim Construction

[HN2] The court construes claims from the vantage point of a person of ordinary skill in the art at the time of the invention. See *Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995)* (en banc), aff'd, *517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996).* However, the court may interpret a term in a patent claim to have a meaning other than the one a person of ordinary skill in the art would give it if it is apparent from the patent and the prosecution history that the inventor intended a different meaning. See *Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1579* (Fed. Cir.), cert. denied, *519 U.S. 911, 117 S. Ct. 275, 136 L. Ed. 2d 198 (1996).*

[HN3] In construing a claim, the court looks first to the intrinsic evidence of record, namely, [*23] the language of the claim, the specification, and the prosecution history. See *Insituform Tech. Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1105 (Fed. Cir. 1996).* The claim language itself defines the scope of the claim, and "a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1552 (Fed. Cir. 1997).* Expert testimony may be considered if needed to assist the court in understanding the meaning or scope of technical terms in a claim. See *Hoechst, 78 F.3d at 1579.* However, reliance on any extrinsic evidence is improper where the claims, specification, and file history unambiguously define the scope of the claim. See *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996).*

[HN4] Although the Court of Appeals for the Federal Circuit has held that claims should be read in light of the specification, *id. at 1582,* the court has repeatedly cautioned against limiting [*24] the scope of a claim to the preferred embodiment or specific examples disclosed in the specification. See e.g., *Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997);* see also *Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989)* (explaining that it is "improper" to read an extraneous limitation from the specification into the claim).

Claim 6 of BASF's *'545* patent is the only claim at issue in this case. Claim 6 claims a process for the catalytic rearrangement of EpB to DHF

> which consists essentially of the rearrangement being catalyzed by a system which contains components A and C from 60 [degrees] to 200 [degrees] C where A is an onium halide, which is substantially soluble in the reaction medium, and C is a Lewis acid or elemental iodine with the proviso that at least one of the components A or C is an iodide.

BASF and Eastman dispute the meaning of two phrases of claim 6. They dispute the meaning of "consists essentially of," and "substantially soluble in the reaction medium."

1. What Does "Consists Essentially Of" Mean?

BASF argues that the phrase "consists essentially of" [*25] means virtually solvent free, and therefore, a small amount of component B, solvent or solubilizer, can be present in the reaction. Eastman argues that "consists essentially of" precludes the use of component B, solubilizers.

BASF argues that the terms solvent and solubilizer are synonymous, that component B includes both terms, and that claim 6 permits the addition of small amounts of either. Eastman distinguishes between the terms, arguing that solvents and solubilizers perform different functions, that component B encompasses solubilizers only, and that claim 6 excludes the addition of component B. Accordingly, before the court construes whether the phrase "consists essentially of" permits the addition of component B, the court must determine whether component B includes both solvents and solubilizers.

The patent describes component B as an organic solubilizer. At column 2, lines 61 to 66, the patent specification explains that because the only requirements that component B has to meet are "bringing about the dissolution of component A and otherwise being stable and inert under the reaction conditions, a large number of substances can be used as component B." Column 2, line 66 [*26] to column 3, line 50 of the *'545* patent gives examples of solubilizers that can be used in the catalyst system, including dioxane, tetrahydrofuran, and certain podands. Thus, the patent defines a solubilizer as an element which dissolves component A.

Column 3, line 68, of the patent discusses certain inert solvents, explaining that specific solvents can be used "for diluting the reaction mixture." The patent specification also gives examples of solvents that can be used for this purpose, including toluene and xylene. Thus, the patent defines a solvent as an element which dilutes the reaction mixture. Accordingly, the patent distinguishes between solubilizers and solvents, teaching that a solubilizer makes component A more soluble in the reaction medium, while a solvent dilutes the reaction medium.

Furthermore, during the prosecution of the *'545* patent, BASF's patent attorney specifically distinguished between solubilizers and solvents, emphasizing that "organic solubilizers" are distinct from solvents. The attorney wrote to the PTO:

> The term "organic solubilizer" is also carefully defined by the Fischer [*'545*] specification as being 'complexing agents for the salts A' or [*27] closely equivalent complexing solvents. This "organic solubilizer" is not an "inert solvent" such as those listed in col. 3, lines 64-68, including xylene and toluene, etc. Fischer makes it quite clear that such "inert solvents" are not suitable as an organic solubilizer but may be optionally added as a diluent.

Thus, the court concludes that solvents and solubilizers have distinct meanings and that component B, an "organic solubilizer," includes solubilizers only.

The court must now determine what the phrase "consists essentially of" means, and whether it permits the addition of component B. The phrase "consists essentially of" is not unique to the *'545* patent. [HN5] The Federal Circuit has stated that the "limited phrase 'consisting essentially of'" does not "exclude the addition of another ingredient which does not materially affect the characteristics of the invention." *Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 666 (Fed. Cir. 1988).* The Federal Circuit has also stated that "consists essentially of" does "close the claims to other ingredients that do alter the basic and novel characteristics of the invention." *Neville Chem. Co. v. Resinall Corp., 915 F.2d 1584, 1990 WL 135903,* [*28] at *1 (Fed. Cir. 1990).

The *'545* patent originally included six claims. Claims 1 to 5 all included component B, an organic solubilizer, as an essential element of the catalyst system. Component B's role in the catalyst system was to bring component A into solution. Claim 6, however, covered a catalyst system in which component A, an onium halide, is "substantially soluble," thereby eliminating the need for an organic solubilizer. The patent specification refers to onium halides as having an "intrinsic solubility." If something is intrinsically soluble, it is inherently capable of dissolving and does not need an additional component to put it into solution. Because the court defines solubilizer as an element that makes component A soluble, it follows that something that is intrinsically soluble does not need a solubilizer to help it dissolve.

The patent specification also states that certain onium halides are soluble enough such that "virtually no addition of solubilizer B is necessary." BASF argues that "virtually no addition" means that some solubilizer B can be added. However, this statement must be read in connection with the following sentence which states that "[a] [*29] procedure of this type [with virtually no addition of solubilizer] is equivalent to the claimed process." This language was part of the patent specification prior to the addition of claim 6. Thus, the "claimed process" referred to is the process covered by claims 1 to 5, in which the addition of solubilizer, regardless of how little, constituted a basic and novel characteristic of the process.

During the prosecution of the original *'545* patent application, which included claims 1 to 5 only, the patent examiner relied on the specification language when he noted that solubilizer may not be necessary when certain halides are used as component A. On November 6, 1990, the examiner suggested what eventually became claim 6 of the *'545* patent when he wrote that "this 'no solubilizer' embodiment is intended to be covered by the claims."

As noted above, one of the "basic and novel characteristics" of claim 6 is that component A is "intrinsically soluble." Because it is "intrinsically soluble" component B does not need to be added to make it soluble. In fact, the reason BASF eventually added claim 6 was because of the patent examiner's recognition that certain onium halides do not need the [*30] addition of component B to bring them into solution. BASF even admits this, stating in their argument that "[a] basic and novel characteristic of claim 6 is that it is a catalytic process for converting EpB to DHF which can be carried out virtually neat." Therefore, the addition of component B, a solubilizer, is not necessary and would alter this inherent trait.

Accordingly, the court concludes that the phrase "consists essentially of" excludes the addition of any component B, a solubilizer.

2. What Does "Substantially Soluble in the Reaction Medium" Mean?

BASF argues that the phrase "substantially soluble in the reaction medium" can be construed in three different ways.

First, BASF argues that the term "reaction medium" is not limited only to the EpB reactant and the DHF product, and that the "reaction medium" includes the chemical components of the reaction or by-products of EpB, such as oligomer. Eastman argues that "reaction medium" means only the EpB reactant and DHF product.

Second, BASF argues that "substantially soluble in the reaction medium" means that small amounts of solubilizer or solvent can be added. Eastman argues that the phrase "substantially soluble in [*31] the reaction medium" means that no solubilizers need to be added.

Third, BASF argues that the phrase "substantially soluble in the reaction medium" only includes a liquid-phase homogenous process, which means a liquid EpB feed, liquid catalysts, and liquid end products. Eastman argues that the phrase does not preclude a process in which EpB is fed in gas form, the catalyst system is liquid, and the end product is in gas form, because having catalysis in a liquid phase is the only phase-related limitation implicit in claim 6.

a. Does the term "reaction medium" include only EpB and DHF?

At column 2, lines 56 to 61 of the *'545* patent, the specification states that "component B of the catalyst system must, because it acts as solubilizer for component A, be chosen such that the particular salts A dissolve in the reaction medium, i.e. in particular in the alkenyloxirane II and in mixtures thereof with the dihydrofuran I which are produced during the reaction." This is the only place in the patent where "reaction medium" is described. Because the language of the patent itself is not clear as to the definition of "reaction medium," the court will turn to the prosecution history for [*32] a definition of the term "reaction medium."

During the prosecution of the *'545* patent, BASF attorneys defined reaction medium as EpB and DHF alone, when they wrote about limiting component A to an onium halide "'which is substantially soluble in the liquid reaction medium,' i.e. in the epoxy-butene [EpB] itself or its dihydrofuran [DHF] product." BASF attorneys also wrote that "Fischer Claim 6 is applicable only to those onium halides which are substantially soluble in the liquid epoxybutene or its products. Otherwise it would be necessary to add the organic solubilizing component B as in Fischer Claim 1." Furthermore, the "advantage of the process of Fischer Claim 6 is that no other solvent is required except the liquid epoxyalkene reactant itself (or its products) as the solvent capable of acting as the organic solubilizer for the onium halide catalyst to produce a single homogenous liquid phase."

Accordingly, the prosecution history demonstrates that the reaction medium consists of the EpB and the DHF only.

b. Does the phrase "substantially soluble in the reaction medium" include the addition of solubilizer?

BASF argues that because component A, the onium halide, [*33] need only be "substantially soluble," some solubilizer can be added. However, there is no evidence that the patent requires that all of component A dissolve. Rather, the patent focuses on the reaction that occurs during the catalytic rearrangement of EpB to DHF. Thus, the onium halide need only be soluble enough for catalysis to occur. Thus, "substantially soluble" does not mean that some solubilizer must be added to dissolve any remaining portion of component A.

Additionally, as noted above, the language used in the prosecution history also demonstrates that the phrase "substantially soluble in the reaction medium" means that no solubilizer is necessary. During the prosecution of the *'545* patent, BASF attorneys contended that the language "substantially soluble in the liquid phase reaction medium" constitutes "an essential limitation which omits any need for a third component which is an organic solubilizer B as set forth in Fischer Claim 1." Furthermore, BASF wrote that "claim 6 was added to the

Fischer U.S. application to provide separate and explicit protection for this two-component catalyst system in the liquid phase reaction." This language makes it clear that claim 6 does [*34] not include the addition of any solubilizer.

Accordingly, the court concludes that the phrase "substantially soluble in the reaction medium" excludes the addition of any solubilizer.

c. Does the phrase "substantially soluble in the reaction medium" exclude gas feed processes?

As noted above, claim 6 precludes the addition of solubilizer because component A, the onium halide, is soluble enough for catalysis to occur without the addition of component B. Because component A is soluble it is capable of being dissolved, and if it is dissolved, it is in a liquid state. Therefore, if a required element of claim 6 is that component A is soluble in the reaction medium, it necessarily follows that the catalyst system must be in liquid phase.

Aside from the requirement that the catalyst system be in liquid phase, claim 6 does not impose any additional limitations on the form in which the catalytic rearrangement occurs. Rather, because claim 6 describes the catalyst system, and the reaction medium, it addresses the point at which catalytic rearrangement occurs, not any time before or after. Accordingly, there is no limitation on whether the EpB is added in gas form, or the DHF is removed [*35] as a gas, so long as the conversion from EpB to DHF occurs in a liquid phase. This comports with the court's construction of the term "reaction medium" to mean only EpB and DHF, as component A must be in liquid form as the EpB converts to DHF.

The court concludes that the only phase-related requirement of claim 6 is that the reactant and the catalyst are dissolved in the same liquid phase. Therefore, the phrase "substantially soluble in the reaction medium" does not exclude gas feed processes. Rather, it only means that the catalysis must occur in a liquid phase.

B. Infringement

BASF argues that Eastman's production of DHF at Longview infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing. Eastman argues that it is not infringing.

1. Does The Longview Process Infringe Claim 6 Of The *'545* Patent?

[HN6] Section 271(a) of the Patent Act states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." *35 U.S.C. § 271*(a).

BASF argues that the Longview process [*36] infringes claim 6 of the *'545* patent because Eastman catalytically rearranges EpB to DHF using a virtually solvent free process including a catalyst system of a Lewis acid and an onium halide which is "substantially soluble in the reaction medium" in a specific temperature range. Thus, BASF argues that the Longview process meets every element of claim 6. Eastman argues that claim 6 excludes the addition of solubilizer, and because the Longview process includes the addition of solubilizer Eastman is not infringing.

The Longview process begins with a catalyst system including onium halide, THF, and Lewis; acid. The purpose of adding the THF to the EpB is to help dissolve the onium halide. Accordingly, consistent with this court's definition, THF acts as a solubilizer because its purpose is to dissolve component A, the onium halide. The *'545* patent specification identifies THF as a solubilizer at column 3, line 59. Thus, at startup the Longview process does not infringe claim 6 of the *'545* patent because of the addition of a solubilizer. However, BASF argues that because the THF is promptly removed from the system, the Longview process is run solubilizer-free and therefore, infringes [*37] claim 6.

As the THF is removed from the system, and the DHF is produced, approximately 3% of the EpB is converted to oligomer. Eastman builds up the oligomer to where it constitutes a substantial proportion of the system, and recycles it back into the system. The purpose of the oligomer is to help keep the onium halide in a liquid state. Accordingly, consistent with this court's definition, the oligomer acts as a solubilizer. Dr. George W. Gokel, Eastman's chemistry expert, testified at trial that the oligomer used in the Longview process is a podand. At column 3, lines 36 to 51, of the *'545* patent, podands are identified as solubilizers. Thus, the Longview process is run with the continuous addition of solubilizer.

The court determined that claim 6 of the *'545* patent precludes the addition of solubilizer. The Longview process uses two different solubilizers, THF and oligomer, in the production of DHF. Accordingly, the Longview process does not infringe claim 6 of the *'545* patent.

2. Is Eastman Wilfully Infringing Claim 6 Of The *'545* Patent?

Because the court concludes that Eastman's production of DHF at Longview does not infringe claim 6 of the *'545* patent, the court concludes [*38] that Eastman is not wilfully infringing claim 6 of the *'545* patent.

C. Invalidity

Eastman argues that claim 6 of the *'545* patent is invalid on the grounds that Eastman's prior reductions to

practice establish priority of invention pursuant to § 102(g). [HN7] Section 102(g) provides that a person is entitled to a patent unless

> before the application's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g). Eastman argues that the gas feed work of Monnier and Low, and Falling's experiments, constitute prior reductions to practice, and that the '208 application disclosed the results of their experiments. BASF argues that claim 6 of the *'545* patent is not invalid because Monnier and Low's work does not meet the limitations of claim 6, and because Falling abandoned, suppressed, [*39] or concealed his experiments.

[HN8] Claim 6 of the *'545* patent is presumed to be valid. See *35 U.S.C. § 282*. Eastman bears the burden of proving invalidity by clear and convincing evidence. See *Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 935* (Fed. Cir.), cert. denied, *498 U.S. 920, 112 L. Ed. 2d 250, 111 S. Ct. 296 (1990)*. Clear and convincing evidence is shown when the trier of fact has "an abiding conviction that the truth of [the] factual contentions [is] highly probable." *Colorado v. New Mexico, 467 U.S. 310, 316, 81 L. Ed. 2d 247, 104 S. Ct. 2433 (1984)*.

1. Does The Work Of Eastman's Scientists Constitute Prior Reduction to Practice Of Claim 6?

[HN9] To show prior reduction to practice, Eastman must show that its work "meet[s] every element of the claimed invention" before August 8, 1989, the priority date of the *'545* patent application. *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1378 (Fed. Cir. 1986)*, cert. denied, *480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987)*. See also *UMC Electronics Co. v. United States, 816 F.2d 647, 651 (Fed. Cir. 1987)*, [*40] cert. denied, *484 U.S. 1025, 98 L. Ed. 2d 761, 108 S. Ct. 748 (1988)* (stating that [HN10] "there cannot be a reduction to practice of the invention here without a physical embodiment which includes all limitations of the claim").

This court has construed claim 6 to mean the catalytic rearrangement of EpB to DHF at temperatures between 60 [degrees] and 200 [degrees] C, using a catalyst system including a Lewis acid and an onium halide that is "substantially soluble in the reaction medium," where the reaction medium includes the EpB and the DHF alone. The court concluded that claim 6 precludes the addition of any solubilizer, but permits the addition of solvent. Additionally, the court concluded that, as long as the catalysis occurs in a liquid phase, claim 6 has no other phase-related requirements. Thus, in order to establish a prior reduction to practice, Eastman must show an experiment that meets all of these elements of claim 6.

In December 1987, Eastman scientists created an EpB team to develop a process for converting EpB to DHF. This team included Falling, Monnier, and Low. In June 1988, Falling began to experiment with different catalyst systems for catalytically [*41] rearranging EpB to DHF. Falling's experiments included EpB in liquid form, liquid-phase catalysis, and the production of liquid DHF.

Eastman asserts that two types of experiments performed by Falling constitute a prior reduction to practice. First, Falling conducted solubilizer-free experiments using a catalyst system of an onium halide and a Lewis acid, and optionally including a solvent. Second, Falling conducted neat experiments, solubilizer- and solvent-free, using a catalyst system of an onium halide and a Lewis acid.

On June 9, 1988, Falling mixed a Lewis acid, an onium halide, and a solvent with EpB at 100 [degrees] C. This produced 4.4% DHF. Falling used tetrabutylammonium iodide as the onium halide. At trial, both Falling and Eastman's chemical engineering expert, Dr. Bruce Gates, testified that this particular onium halide is substantially soluble in EpB and DHF, the reaction medium. Falling conducted similar experiments on June 15, and June 28, and June 30, 1988, switching the temperature in the first, switching the Lewis acid in the second, and switching the solvent in the third. On October 3, 1988, Falling catalytically rearranged EpB to DHF by mixing a Lewis acid [*42] (tributyltin iodide), an onium halide (tetrabutylphosphonium iodide), and a solvent (toluene), at 150 [degrees] C.

Falling also conducted three neat experiments, without any solubilizer or solvent. On July 6, 1988, Falling obtained 71.2% DHF when he mixed EpB with a Lewis acid (zinc iodide) and an onium halide (tetrabutylammonium iodide) at 66 [degrees] to 70 [degrees] C. In a memo written two days latter to the EpB team, Falling reported that this mix of zinc iodide and tetrabutylammonium iodide is the "best catalyst system studied thus far." On July 18, and July 27, 1988, Falling conducted two more neat experiments, both of which resulted in the production of trace amounts of DHF.

While Falling conducted his experiments, Monnier and Low were also experimenting with various catalyst combinations to convert EpB to DHF. In November 1988, Monnier and Low began to experiment with the onium halide, Lewis acid catalyst system that Falling found so successful to the catalytic rearrangement of EpB to DHF. Between November 1988 and January 1990, Monnier and Low ran numerous experiments converting EpB to DHF using a catalyst system of a Lewis acid and an onium halide at 110 [degrees] [*43] to 185 [degrees] C. All of these experiments were conducted without solvent or solubilizer.

Monnier's and Low's experiments were all gas feed. However, the court has construed claim 6 to mean that only the catalysis must occur in liquid phase. Both Monnier and Low testified at trial that the catalysis occurred in a liquid phase. Monnier stated that

> somewhere in this region after the tetraoctylammonium iodide has melted and formed a liquid phase, we have a situation were the EpB, which was added as a gas composition, actually dissolves into the liquid octyl ammonium iodide and now we have a classic situation of homogenous catalysis where the reaction is occurring between EpB in the liquid phase and [octyl] ammonium iodide which is liquid-phase film.

Accordingly, all of these experiments conducted by Falling, Monnier, and Low, resulted in the catalytic conversion of EpB to DHF using component A, an onium halide, where component A is substantially soluble in the reaction medium, and component C, a Lewis acid, at the relevant temperature range. Although some of these experiments included the addition of a solvent, none included solubilizer, component B. Falling's, Monnier's, [*44] and Low's experiments, with or without solvent, successfully converted EpB to DHF meeting all of the limitations of claim 6.

Accordingly, Eastman has shown by clear and convincing evidence that these experiments constitute prior reductions to practice of claim 6 of the *'545* patent before August 8, 1989, and unless Eastman abandoned, suppressed or concealed the experiments, they establish priority of invention pursuant to § 102(g).

2. Did Eastman Abandon, Suppress, Or Conceal Its Experiments?

BASF admits that Falling's neat experiments are within the scope of claim 6. However, BASF argues that Eastman abandoned, suppressed, or concealed, these experiments. Furthermore, as discussed above, BASF argues that Monnier's and Low's experiments are not within the scope of claim 6, and therefore, the question of abandonment, suppression, or concealment is not relevant to their work.

[HN11] In order to show that Eastman did not abandon, suppress, or conceal experiments within the scope of claim 6, Eastman must show that it disclosed the process of claim 6 in a manner that would "bring the benefit of the knowledge of [the] invention" to the public, and that it did not unreasonably delay this [*45] disclosure. See *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n, 54 F.3d 756, 761 (Fed. Cir. 1995).* See also *National Presto Indus., Inc. v. Black & Decker (U.S.) Inc., 1995 U.S. App. LEXIS 15568,* Nos. 92-1388, -1476, *1995 WL 367072,* at *6 (Fed. Cir. June 20, 1995) (stating that [HN12] it "is necessary to consider the nature and extent of activity during the period between reduction to practice and the filing of the patent application"); *Lutzker v. Plet, 843 F.2d 1364, 1366 (Fed. Cir. 1988)* (noting that an invention that is not publicly disclosed is deemed abandoned, suppressed, or concealed).

Eastman filed the '208 patent application on March 8, 1990. This application primarily disclosed the gas feed, liquid phase catalyst work done by Monnier and Low, which constitutes prior reductions to practice of claim 6. Accordingly, they did not abandon, suppress, or conceal their experiments. Even if the court concluded that Monnier's and Low's work was not a prior reduction to practice of claim 6, the evidence shows that Eastman did not abandon, suppress, or conceal Falling's experiments which constitute prior reductions to practice.

Falling, Monnier, and Low [*46] worked from the early summer 1988 to the beginning of 1990 to create a successful process for catalytically rearranging EpB to DHF. During this time, Falling conducted numerous experiments which constitute prior reductions to practice of claim 6. Falling's monthly reports documented the progress of these experiments. Over a year after Falling first began to experiment with different catalyst systems, he wrote in an August 1, 1989, memo to the EpB team, that "the screening of catalyst systems for the homogenous rearrangement of EpB to 2,5-DHF is still in progress." Accordingly, it is clear that Eastman did not abandon Falling's experiments producing DHF from EpB. See *Checkpoint 54 F.3d at 762* (finding that a four year delay between the time the inventor disclosed his invention to his employer, "further tested" and improved the invention, and worked towards commercializing it, "establish that [the inventor] was diligent in working toward commercializing" the security system, and did not constitute abandonment).

Although Eastman did not abandon Falling's experiments which establish prior reduction to practice, if

Eastman suppressed or concealed them, they will not [*47] invalidate claim 6. Eastman filed the '208 application in March 1990, and the CIP in December 1990. BASF argues that neither the original application nor the CIP disclose Falling's work, and therefore, Eastman suppressed or concealed Falling's prior reductions to practice of claim 6.

Although the '208 application did not include any working examples of Falling's experiments, it generally covered Falling's work. The '208 application disclosed a process for the catalytic rearrangement of EpB to DHF using a catalyst system of an onium halide and a Lewis acid. In June 1988, Falling first discovered that mixing an onium halide and a Lewis acid would act as a successful catalyst. Monnier and Low began using this catalyst system in November 1988, after seeing the results Falling was obtaining with it.

The '208 application also discussed the optional use of an inert solvent, which Falling had experimented with. In particular, on page 14, lines 14 to 24, the '208 application states that the "organic onium iodide, optionally, in combination with a Lewis acid co-catalyst, may be used with an inert organic solvent if desired." It further refers to the "optional, inert organic solvent."

Furthermore, [*48] on page 3, lines 5 to 8 of the '208 application, it states that the process contemplated includes recovery of the DHF produced by various methods, including "decantation" and "filtration." Monnier testified at trial that both decantation and filtration mean the removal of a liquid-phase product. Falling's work was done entirely in liquid phase, whereas Monnier's and Low's work was gas feed of EpB and a gas product of DHF.

Eastman filed the CIP on December 14, 1990. The CIP was based on Falling's and Lopez-Maldonado's invention report. The CIP described the catalyst systems made up of onium halides and Lewis acids that Falling had worked on. Furthermore, the CIP added working examples of liquid phase experiments to the '208 application. Thus, the CIP clearly disclosed Falling's work on converting EpB to DHF.

[HN13] The Federal Circuit has stated that "when determining whether an inventor has abandoned, suppressed, or concealed an invention, a period of delay between completion of the invention and subsequent public disclosure" is not always of legal significance. *Checkpoint, 54 F.3d at 761.* Falling last conducted a reduction to practice of claim 6 on October 3, 1988. Eastman [*49] filed the '208 patent application on March 8, 1990, approximately seventeen months later. Eastman filed the CIP on December 14, 1990, approximately twenty-six months later. The amount of time that elapsed between Falling's last reduction to practice and the filing of the '208 patent application, and even the CIP, does not demonstrate suppression or concealment. See e.g., *Cochran v. Kresock, 530 F.2d 385, 393 (C.C.P.A. 1976)* (in a case involving a delay of over 18 months, stating that [HN14] "mere delay, without more, is insufficient" to demonstrate abandonment, suppression, or concealment); *Fisher and Speer v. Gardiner and Aymami, 215 U.S.P.Q. 620* (PTO Bd. of App. 1981) (finding that a delay of 25 months between reduction to practice of the invention and filing the patent application did not constitute suppression or concealment).

In *Engelhardt v. Judd, 54 C.C.P.A. 865, 369 F.2d 408, 412 (C.C.P.A. 1966),* the United States Court of Customs and Patent Appeals stated that [HN15] scientists should be given a reasonable amount of time to refine their invention. The Englehardt court stated that

> [a] reasonable amount of time should be allowed [*50] for completion of the research project on the whole series of new compounds, a further reasonable period should then be allowed for drafting and filing the patent application(s) thereon, without subjecting the prior inventor or his assignee to the risk of forfeiture of valuable patent rights due to alleged concealment or suppression of the invention.

Id. The seventeen to twenty-six month period that elapsed between Falling's reduction to practice and the filing of the '208 application and the CIP constitutes a reasonable amount of time. Thus, the court concludes that Eastman did not suppress or conceal the work Falling did during the summer and fall of 1988.

The court concludes that Eastman did not abandon, suppress, or conceal the prior reductions to practice of claim 6 of the *'545* patent, and therefore, claim 6 is invalid on the grounds of priority of invention pursuant to § 102(g).

III. CONCLUSION

For the reasons stated above, the court concludes that Eastman is not infringing claim 6 of the *'545* patent, claim 6 is invalid on the grounds of priority of invention pursuant to § 102(g), and Eastman did not abandon, suppress, or conceal the invalidating prior [*51] reductions to practice. The court will enter an order in accordance with this memorandum opinion.

MITEK EXHIBIT 29

LEXSEE 2006 US APP LEXIS 16665

MOMENTUS GOLF, INC., Plaintiff-Appellant, v. SWINGRITE GOLF CORPORATION (also known as Swingrite Corporation), Defendant-Appellee, and GRIPS FORE GOLF and J & M GOLF, INC., Defendants.

05-1614

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006 U.S. App. LEXIS 16665

June 30, 2006, Decided

NOTICE: [*1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING CITATION TO UNPUBLISHED OR NONPRECEDENTIAL OPINIONS OR ORDERS.

PRIOR HISTORY: *Momentus Golf v. Swingrite Golf Corp., 2005 U.S. Dist. LEXIS 17850 (S.D. Iowa, Aug. 23, 2005)*

CASE SUMMARY:

PROCEDURAL POSTURE: In a patent infringement action, plaintiff applicant sought review of a decision of the U.S. District Court for the Southern District of Iowa, which granted summary judgment in favor of defendant golf corporation, finding that the prosecution history of the patent in question, which covered a golf club swing aide, disclaimed any device having more than 10 percent club head weight.

OVERVIEW: The issue was whether, during the prosecution of the patent, the applicant disclaimed devices having a club head weight of more than 10 percent. The appellate court concluded that the statement in the prosecution history that a hollow device having 10-25 percent club head weight could not meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock was open to more than one reasonable interpretation. Thus, according to the appellate court, the statement was not a clear and unmistakable disclaimer of all devices having 10-25 percent club head weight. At most, it disclaimed hollow devices having 10-25 percent club head weight. Accordingly, the federal district court erred in its claim construction to the extent that it determined that all devices having 10-25 percent club head weight fell outside of the scope of the claims of the patent. Therefore, the appellate court vacated the judgment of the district court and remanded for further proceedings consistent with its opinion.

OUTCOME: The appellate court reversed and remanded.

LexisNexis(R) Headnotes

Civil Procedure > Appeals > Standards of Review > De Novo Review
Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > Infringement Actions > Summary Judgment > Claim Evaluation
Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review
[HN1] The U.S. Court of Appeals for the Federal Circuit reviews a district court's grant of a motion for summary judgment of no infringement de novo. Similarly, it reviews the district court's claim construction de novo.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > Infringement Actions > Prosecution History Estoppel > Abandonment & Amendment
[HN2] The purpose of the doctrine of prosecution disclaimer is to prevent a patentee from recapturing through claim interpretation meanings that he disclaimed during prosecution. Any such disclaimer must be clear and unmistakable. The U.S. Court of Appeals for the Federal Circuit has explained, however, that there is no clear and unmistakable disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of

which is consistent with a proffered meaning of the disputed term.

JUDGES: Before SCHALL, Circuit Judge, ARCHER, Senior Circuit Judge, and DYK, Circuit Judge. Opinion for the court filed by Senior Circuit Judge ARCHER. Dissenting opinion filed by Circuit Judge SCHALL.

OPINIONBY: ARCHER

OPINION: ARCHER, Senior Circuit Judge.

Momentus Golf, Inc. ("Momentus") appeals the judgment of the United States District Court for the Southern District of Iowa granting Swingrite Golf Corporation's ("Swingrite") motion for summary judgment. *Momentus Golf, Inc. v. Swingrite Golf Corp., 2005 U.S. Dist. LEXIS 17850, No. 4:02-cv-40252 (S.D. Iowa Aug. 23, 2005)*. Because the district court erred in concluding that the prosecution history of *U.S. Pat. No. 5,582,407* ("the *'407 patent*") disclaimed any device having more than 10% club head weight, we vacate the court's judgment and remand for further proceedings.

I

The *'407 patent* is directed to a golf club swing aide. Relevant to this appeal, claim 1 of the *'407 patent* states:

> A golf swing trainer [*2] consisting essentially of a golf grip fixed about one end of a length of round stock which is solid through it[s] length and cross-section, sol[i]d round stock, said trainer having a center of gravity substantially centered at a midpoint of a longitudinal axis of said length of roundstock, and the weight of said round stock being heavier than a typical golf club so that repeated swings of the trainer establishes a muscle memory of the path of the swing, breaking down the incorrect muscle memory and building the correct muscle memory of the path of the swing.

'407 patent, col. 5, ll. 4-13. Claim 9 adds the element of a "golf club head fixed to another end of said length of stock." Id. at col. 4, ll. 12-13.

Momentus sued Swingrite for infringement of the *'407 patent*. n1 When construing claim 1, the district court concluded that "during the prosecution of its claim, Momentus conceded that the center of gravity of a device with a club head weight of 10-25 percent would not be substantially centered at a midpoint of the shaft and therefore cannot meet the requirements of Momentus' claims." *Momentus Golf, Inc. v. Swingrite Golf Corp., 312 F. Supp. 2d. 1134, 1143 (S.D. Iowa 2004)* [*3] ("Claim Construction Order"). Based on this perceived disclaimer and the fact that the "novel property of the Momentus trainer is that its center of gravity is substantially centered at the midpoint of its solid round shaft," *id. at 1144*, the district court "construe[d] the phrase 'consisting essentially of' in Claim 1 as excluding any element [that] if added to the device would constitute more than 10 percent club head weight, because such an element would materially alter the novel property of the invention," *id. at 1144*.

> n1 Grips Fore Golf and J & M Golf were named defendants in the originally filed suit. Neither party, however, participated in this appeal.

Following the district court's claim construction ruling, Swingrite filed a motion for summary judgment of no infringement, which the district court granted. Momentus appeals, arguing that there was no prosecution disclaimer and that the district court erred by reading into the claim a requirement that the weight of the club head constitute less than ten percent of the device's weight. We have jurisdiction pursuant to *28 U.S.C. § 1295(a)(1)*.

II [*4]

[HN1] We review the district court's grant of Swingrite's motion for summary judgment of no infringement de novo. *Hilgrave Corp. v. McAfee Assocs., Inc., 224 F.3d 1349, 1352 (Fed. Cir. 2000)*. Similarly, we review the district court's claim construction de novo. *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)* (en banc).

The issue in this case is whether, during the prosecution of the *'407 patent*, the applicant disclaimed devices having a club head weight of more than 10%. [HN2] The purpose of the doctrine of prosecution disclaimer is to prevent a patentee from recapturing through claim interpretation meanings he disclaimed during prosecution. *SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005)* (citations omitted). Any such disclaimer must be clear and unmistakable. Id. (stating "[w]hen the patentee makes clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection, the courts limit the relevant claim term to exclude the disclaimed matter" (citing *Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003)*)). [*5] We have explained, however, that "[t]here is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent

with a proffered meaning of the disputed term." *Id. at 1287* (citing *Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed. Cir. 2004)*; *Cordis Corp. v. Medronic Ave, Inc., 339 F.3d 1352, 1359 (Fed. Cir. 2003)* (finding no disclaimer because "the statements in the prosecution history are subject to multiple reasonable interpretations, they do not constitute a clear and unmistakable departure from the ordinary meaning of the term [at issue]").

During prosecution of the *'407 patent*, the examiner initially rejected the claims as being anticipated by or obvious in view of *U.S. Pat. No. 3,231,281* ("Wallo"). Wallo describes a golf club swing aide that "provide[s] effective and proper toning and strengthening of the body muscles while simultaneously and automatically guiding the body movements into proper coordination." Wallo at col. 1, ll. 31-36. It accomplishes this by using a "club" that is three to five times the weight of a standard golf club. [*6] Id. at col. 2, ll. 9-10. Wallo's golf club swing aide is described as hollow, id. at col. 1, ll. 71-72, col. 2, line 37; however, the patent also explains that if the shaft and head are made of lighter material, "the proper weight may be provided by filling the hollow shaft and head with a material of appropriate density," id. at col. 2, ll. 36-39.

In responding to the examiner's rejection, the '407 applicant distinguished the claimed invention from Wallo:

> The shaft [in Wallo] is hollow. The overall weight of the trainer is such as to require a firmer grip, to strengthen the hands and to slow the swing. The down swing is resisted by the "excessive weight of the club." The trainer causes "toning and strengthening of the muscles by swinging the excessive weight." Unlike Wallo, applicant's trainer has a solid shaft, uses no club head and substantially 100% of the trainer weight is non club head weight. A hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock. Furthermore, as explained above, and as set forth in greater detail [*7] in claim 11 and in even greater detail in claim 12 of the present application, the claimed weighting of applicant's device is related to changing the memory and not the strength of the muscles involved in the swing and to changing the path of the swing due to balance rather than changing the speed of the swing due to weight. Applicant therefore submits that applicant's present invention is neither anticipated by Wallo, which does not disclose the structure claimed by applicant, nor obvious over Wallo, which teaches an entirely different concept of golf swing training and is not applicable to the principles taught by applicant.

(key sentence in dispute emphasized). Because the claimed invention could not be distinguished from Wallo solely on the grounds of being solid, the district court interpreted the underlined sentence above as identifying another distinction between the claimed invention and Wallo; namely, club head weight. Based on this, the court viewed the statement as a "conce[ssion] that the device with a club head having 10-25 percent of its weight at the end of the shaft opposite the grip would fall outside the scope of the [claimed] trainer." Claim Construction [*8] Order at 1143. This reading is fathomable. However, we agree with Momentus that this sentence is open to another interpretation: the applicant was simply stating that a hollow club having 10-25% club head weight (a device described by Wallo) could not meet the claim limitation in the *'407 patent* that the club shaft have a center of gravity at the center of a solid shaft. Such a reading does not suggest that all clubs having a 10-25% club head weight are outside the scope of the invention; rather, only hollow clubs with such a characteristic fall outside the scope of the claims.

Interpreting the prosecution history in this manner does not affect the applicant's argument that the claimed invention was not anticipated by, or obvious in view of, Wallo. The applicant of the *'407 patent* distinguished the claimed invention from Wallo on grounds other than "solidness"; namely, that the two devices functioned in totally different ways. Specifically, the applicant noted that the claimed invention worked by changing the user's muscle memory and the path of the user's swing due to balance while the Wallo device worked by strengthening the user's muscles and changing the speed of the [*9] user's swing due to weight. The examiner recognized this as the distinguishing feature of the claimed invention. Thus, in an examiner's amendment prior to allowance, the examiner added language to the claim to reflect this distinction; namely, "and the weight of said round stock being heavier than a typical golf club so that repeated swings of the trainer establishes a muscle memory of the path of the swing, breaking down the incorrect muscle memory and building the correct muscle memory of the path of the swing."

We conclude that the statement in the prosecution history that "[a] hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock," (emphasis added), is open to more than one reasonable interpretation. Thus the statement was not a clear and unmistakable disclaimer of all devices having 10-25% club head weight. See *SanDisk, 415 F.3d at 1287*; *Cordis, 339 F.3d at 1359*. At most it disclaims hollow devices having 10-25% club head weight.

Accordingly, the district court erred in its claim construction to the extent [*10] it determined that all devices having 10-25% club head weight fall outside of the scope of the claims of the *'407 patent*. Therefore, we vacate the judgment of the district court and remand for further proceedings consistent with this opinion.

DISSENTBY: SCHALL

DISSENT: SCHALL, Circuit Judge, dissenting.

I would affirm the grant of summary judgment of non-infringement. In my view, the district court correctly held that, during prosecution of the application that resulted in *U.S. Patent No. 5,582,407* ("the *'407 patent*"), the inventor disclaimed golf swing trainers having more than 10% club head weight.

Claim 1 of the *'407 patent* describes a golf swing trainer with a shaft of "sol[i]d round stock, said trainer having a center of gravity substantially centered at a midpoint of a longitudinal axis of said length of round stock." *'407 patent*, col. 5, ll. 6-8. Claim 1 was rejected during prosecution as anticipated or obvious in view of *U.S. Patent No. 3,231,281* ("the Wallo patent"). The inventor responded to the rejection by distinguishing the golf swing trainer disclosed by the Wallo patent as follows:

> In Wallo, from 75 to 90% of the weight of the trainer is in the shaft, resulting [*11] in from 10 to 25% of the weight being in the head of the trainer (col 2, lines 18-24). The shaft is hollow (col 2, lines 25-40). The overall weight of the trainer is such as to require a firmer grip, to strengthen the hands and to slow the swing (col 2, lines 41-49). The down swing is resisted by the "excessive weight of the club" (col. 2, lines 58-59). The trainer causes "toning and strengthening of the muscles by swinging the excessive weight" (col. 2, lines 69-70). Unlike Wallo, applicant's trainer has a solid shaft, uses no club head and substantially 100% of the trainer weight is non club head weight. A hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock. Furthermore, as explained above, and as set forth in greater detail in claim 11 and in even greater detail in claim 12 of the present application, the claimed weighting of applicant's device is related to changing the memory and not the strength of the muscles involved in the swing and to changing the path of the swing due to balance rather than changing the speed of the swing due to weight. [*12] Applicant therefore submits that applicant's present invention is neither anticipated by Wallo, which does not disclose the structure claimed by applicant, nor obvious over Wallo, which teaches an entirely different concept of golf swing training and is not applicable to the principles taught by applicant.

(emphasis added). Based on the above passage, the district court found that the inventor disclaimed trainers with a club head weight between 10-25% of the weight of the trainer because those trainers would not have a center of gravity substantially centered at the midpoint of the trainer's shaft. *Momentus Golf, Inc. v. Swingrite Golf Corp., 312 F. Supp. 2d 1134, 1143 (S.D. Iowa 2004)*.

The majority concludes, however, that the above-quoted passage does not comprise a "clear and unmistakable disclaimer" of devices having 10-25% club head weight because the underlined portion of the passage can reasonably be interpreted as disclaiming golf swing trainers with a hollow shaft instead of disclaiming golf swing trainers with 10-25% club head weight. Majority Op. at 5-6. I am unable to read the passage as the majority reads it.

I read the underlined sentence of [*13] the passage as clearly and unmistakably disclaiming both (i) a device having 10-25% club head weight and also (ii) a device having a hollow shaft. The underlined sentence states, "A hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock." (emphases added). The Wallo device differs, according to this key sentence, because it is (i) hollow rather than solid and (ii) has 10-25% club head weight as opposed to a center of gravity substantially at

the center of the shaft. The remainder of the passage, it seems to me, confirms that the underlined sentence is making two distinct disclaimers. In the first sentence of the passage, the inventor sets forth the framework for the club head weight disclaimer by noting that the Wallo device has 10-25% of its weight in the club head. In the second sentence, the inventor states that the Wallo device has a hollow shaft. Thus, the inventor sets forth these two features of the Wallo device separately. The inventor then states that "[u]nlike Wallo, applicant's trainer has a solid shaft, uses no club [*14] head and substantially 100% of the trainer weight is non club head weight." (emphases added). Again, the composition of the shaft and the club head weight are set forth as separate features by the inventor. Thus, in my view, the key sentence and the surrounding passage clearly and unmistakably disclaim both devices with a hollow shaft and devices with 10-25% club head weight. I think that this is the only reasonable interpretation of the above passage. In short, I agree with the district court's construction of "substantially centered," which limited claim 1 of the *'407 patent* to devices with less than 10% club head weight. I would thus affirm the grant of summary judgment of non-infringement. I therefore respectfully dissent.

MITEK EXHIBIT 30

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

D. If The Claims Of The 446 Patent Are Construed To Mean That "PE" Includes UHMW PE, Then The 446 Patent Is Non-obvious Over Burgess And i) Cohan; ii) The DSM Brochure; And/Or iii) The Harpell Patents

86. My below opinions assume that the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE.

1. It Is My Opinion That Claims 1, 2, 8, 9 and 12 of the 446 Patent Are Not Invalid For Obviousness Over Burgess In View Of Cohan

87. Dr. Mukherjee states that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obviousness over Burgess in view of Cohan. I disagree. Below I discuss the teachings of Burgess and Cohan to one of ordinary skill in the art between 1988 and 1992.

a) The Scope And Content Of Burgess

88. Burgess discloses fishing lines (Ex. 7 at 1), not suture or medical devices. Burgess discusses certain desirable properties of a fishing line, but does not mention certain suture properties, such as knot security or knot strength (Ex. 7 at 1). Burgess does state that fishing lines "require… non-stretchability" (Ex. 7 at 1). Burgess states that "non-stretchability" is a fishing line requirement, not a preference (Ex. 7 at 1).

89. Burgess further discloses a fishing line that should have a "braided construction" (Ex. 7 at 1). Burgess discloses that some filaments are of "high tensile polythene thread" and other filaments are "polyester and/or nylon" (Ex. 7 at 1). But Burgess does not disclose what kind of "braided construction" he envisioned, how to construct the braid which he references, nor how to use the materials in the "braided construction" he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone

should be in the core, whether it should be in the sheath alone, or in the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

90. In fact, the Burgess disclosure is at most two double-spaced pages. Burgess has no drawings; Burgess provides no working detail or explanation whatever of the braided fishing-line construction which he references. Nor does he provide any description of how to make the "braided construction" to which he refers or the type of equipment that should be used to fabricate the "braided construction" for a fishing line.

91. Burgess discloses the use of high molecular weight polythene in a fishing line. However, one of ordinary skill in the art would know that high molecular weight polythene is a lubricious material with poor knot security and knot tie down characteristics. Burgess does not disclose how to overcome these characteristics of high molecular weight polythene. Notably, Mr. Grafton, former Arthrex employee and developer of FiberWire, also stated that UHMW PE was typically used for fishing line and did not have acceptable knot tie down characteristics for use in sutures (Ex. 14 at 1:14-20). Mr. Grafton also stated that the poor knot slippage of UHMW PE was due to its lubricity (Ex. 12 at 53). Thus, Burgess discloses high molecular weight polythene, which is known to be a lubricous material, but does not describe how to construct an acceptable suture with UHMW PE.

92. I disagree with Dr. Mukherjee about the scope and content of Burgess. Dr. Mukherjee states that "the Burgess application discloses every limitation of claim 1 of the '446 patent . . . except that Burgess is not a sterilized suture" (Mukherjee at 17). But Dr. Mukherjee does not provide any analysis as to where the claimed limitations are

found in Burgess. Nor does he explain why Burgess necessarily teaches the braid claimed in the 446 patent, as opposed to some other braid construction. Thus, I disagree with his reading of Burgess.

93. Dr. Mukherjee uses the prosecution history of the 446 patent to support his reading of Burgess. I disagree that the prosecution history supports his analysis. Dr. Mukherjee cites to the Examiner's statement that "Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon," and suggests that the Examiner stated that the "braided construction" of Burgess was the same as the claimed "heterogeneous braid" of yarns in "direct intertwining contact." But the Examiner never said this. Notably, the Examiner never stated that Burgess discloses the claimed "heterogeneous braid' of yarns in "direct intertwining contact." Rather, the Examiner only stated that Burgess disclosed a "braided construction," not any specific braided construction, and then concluded it would have been obvious in light of Burgess to form the claimed invention of then pending claims 21-24. Thus, contrary to Dr. Mukherjee's suggestion, the Examiner never stated that Burgess discloses a heterogeneous braid of UHMW PE and Polyester or nylon in "direct intertwining contact" as claimed in the 446 patent.

b) The Scope And Content Of Cohan

94. Cohan discusses the use of an ultra strong polyethylene fiber in an ophthalmic suture. According to Cohan, the "polyethylene fibers are monofilaments with a ribbon shape." It also describes three monofilaments made from nylon, polypropylene, and polyester. The Cohan article discusses testing each of these monofilaments. The testing results are summarized in Figs. 2-4 and Tables 1-3. Figure 2 shows that a continuous filament of polyethylene has a greater tensile strength at break than the

c) The Differences Between Burgess And Cohan And Claim 1 of the 446 Patent Are Significant

103. There are many differences between claim 1 of the 446 patent and the combination of Burgess and Cohan. These differences indicate the non-obviousness of claim 1 of the 446 patent.

104. Claim 1 of the 446 Patent claims a suture. Burgess only describes a fishing line.

105. Claim 1 of the 446 Patent claims a heterogeneous braid where at least one set of yarns from the first group is in direct intertwining contact with at least one yarn from the second group. Burgess does not teach this. In fact, Burgess is entirely silent on the construction of the fishing line or its method of assembly. Thus, Burgess does not teach the braid recited in claim 1 of the 446 Patent.

106. Also, because Burgess does not describe the braided construction he references and does not describe how to make it, Burgess does not enable one skilled in the art between 1988 and 1992 to make and use a suture of claim 1 of the 446 Patent. I do not understand how Dr. Mukherjee considers Burgess to be detailed enough to teach one of ordinary skill in the art in 1992 how to make and use the claimed heterogeneous braid of the 446 Patent, and at the same time opine that the 446 Patent, which is much more detailed than Burgess, does not enable one of skill in the art to make and use the invention claimed in the 446 Patent. Burgess simply does not describe any type of braiding construction, braiding equipment or any braid manufacturing or processing.

107. Likewise, Cohan does not teach the invention of claim 1 of the 446 Patent. Nor does Cohan fill in the gaps left by Burgess. Cohan does not teach a heterogeneous braided suture. Further, the Cohan article does not teach the materials recited in claim

discussed below there is no motivation based on their teachings or the level of skill in the art for several reasons.

111. First, because of the significant differences between Burgess and Cohan and claim 1 of the 446 patent, one of ordinary skill in the art would not have been motivated between 1988 and 1992 to modify Burgess to form the claimed invention. For example, neither describes the claimed heterogeneous suture braid of claim 1 of the 446 Patent, and there is no motivation or suggestion to combine the references to form the claimed braided suture.

112. Second, because Burgess does not describe knot security or knot strength, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of Burgess to make a suture. Knot security and knot strength are two important suture properties. Therefore, Burgess' discussion of different requirements for fishing line and failure to mention knot strength or knot security would cause one of ordinary skill in the art not to be motivated to use Burgess' teachings in designing a suture.

113. Third, Cohan recognizes that monofilament PE has lower knot holding strength and posits overcoming this problem by tying more complex knots. Burgess says nothing about knot holding strength or how to solve the issues raised by Cohan. Thus, one of ordinary skill in the art would not have been motivated to combine Burgess and Cohan to form the claimed invention because he would have focused on trying to resolve the knot holding strength issues raised by Cohan by tying different knots.

114. Fourth, Cohan teaches that monofilament UHMW PE had disadvantages including lower knot holding strength, requiring more complex knots, spontaneous

untying, and unraveling, leading to irritation. Given these problems with the UHMW PE monofilament in Cohan, one of ordinary skill in the art having read Cohan between 1988 and 1992 would not have been motivated to further pursue using UHMW PE without first solving these issues.

115. Fifth, even assuming that one of ordinary skill in the art would have been motivated to pursue the teachings of Cohan, Cohan teaches away from braiding. Cohan teaches trying to design a suture that was stronger than multifilament silk suture, but still had silk's handling properties by tying more complex knots. One of ordinary skill in the art between 1988 and 1992, who had read Cohan, would have focused on monofilaments, tying different types of knots, and eliminating unraveling, not braiding.

116. I have read Dr. Mukherjee's report and Dr. Mukherjee does not specify any motivation for combining the Burgess reference with the Cohan article. He also ignores the differences between the monofilament described in Cohan and the claimed invention of the 446 Patent and the problems noted by Cohan with UHMW PE. Thus, I disagree with his opinion.

117. I note that Dr. Mukherjee states that "it would have been obvious to a person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture" (Mukherjee at 18). I disagree for the reasons set forth above, but note that the general problem with this statement is that Burgess does not disclose any specific braid construction. Thus, one of ordinary skill in the art reading Burgess in 1992 would not have been able to just simply use a braid disclosed by Burgess as a suture, as Dr. Mukherjee suggests.

Burgess, Burgess does not disclose any particular braid, and he would be led down a path of designing a suture to achieve the fishing line properties disclosed in Burgess, not a suture that maximizes suture properties. Burgess says nothing about how to make a braid to achieve knot security or knot strength.

195. At trial, I may use demonstrative exhibits that I have not yet created to further explain my opinions.

Dated: March 24, 2006

Matthew Hermes Ph.D.

HERMES EXPERT REPORT
EXHIBIT 7

(12) UK Patent Application (19) GB (11) 2 218 312 A

(43) Date of A publication 15.11.1989

(21) Application No 8911088.6

(22) Date of filing 15.05.1989

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(51) INT CL*
A01K 91/00, D04C 1/12

(52) UK CL (Edition J)
A1A A19
D1K K14
U1S S1022

(56) Documents cited
None

(58) Field of search
UK CL (Edition J) A1A, D1K
INT CL* A01K, D04C

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(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyesterer and/or nylon, and the braid may be coated with a sheath of polyurethane.

GB 2 218 312 A

2210512

"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

CLAIMS

1. A fishing line of braided construction, some braid filaments being of high tenacile polythene thread and other filaments being of pollyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester maulti-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monorfilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.

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HERMES EXPERT REPORT
EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs. CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

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Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

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A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

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A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

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That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

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A. I said they are related.
Q. Okay. They're your terms. I just want to understand them because when we ask questions, I want to make sure we're both on the same page, because there's a lot of terms that we're throwing around, and some people have different definitions and some people have different understandings of what they mean, so I want to know that when I ask you a question and I ask you a question about knot tiedown that we're both talking about the same thing so there's no misunderstanding what we're talking about.
A. I've told you they were closely related.
Q. Right. But closely related doesn't tell me what knot tiedown is in your mind, so I'm trying to figure out what it means in your mind. So now I've heard you say that it's the ability to approximate the tissue and hold it in place through biomechanical forces?
A. (Witness nods head affirmatively).
Q. I heard you say the size of the knot bundle is part of knot tiedown?
A. (Witness nods head affirmatively).
Q. And by size of the knot bundle, you are referring to how big the knot is when it's tied?
A. Correct.
Q. Anything else included within knot tiedown in your mind?

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A. Not that I can think of right now.
Q. Okay. So in evaluating the Tevdek suture, did you evaluate the Tevdek suture for knot tiedown characteristics?
A. Evaluated for knot strength and straight pull.
Q. How about knot tiedown characteristics?
A. There is no test report that would have knot tiedown as -- as part of the characteristics that were tested.
Q. You said there's no test report. And my question -- that does not necessarily answer the question.
MR. SOFFEN: I think he answered it no at the beginning of the answer.
Q. That's not what the record says.
A. I told you it was a term that we didn't use directly. Knot tiedown -- "knot tiedown" was not used. So the answer to your question then is no.
Q. No? Okay. How about the Pearsalls suture that was polyester? Was that evaluated for knot tiedown characteristics?
A. No.
Q. Okay. How about the term "knot security"? Are you familiar with that term?
A. Yes.
Q. What does knot security mean to you?

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A. The ability of the knot to not slip and to maintain the inner loop linear section that was tied with the knot and hold -- and maintain that during biomechanical forces without slippage.
Q. What do you mean by the inner loop linear section of the knot?
A. When you tie a knot, you're tying it most of the time to bone and tissue. There's -- If you tie a knot, then there's a loop; okay? The knot slippage would be measured as an increase in that loop diameter.
Q. Is there a standard test for that?
A. What do you mean standard test?
Q. A test -- Well, let me rephrase the question.
A. Is there any test for it? Or I don't understand the question.
Q. Let me rephrase the question. Was there a test that you are familiar with that you generally used to evaluate knot security?
A. Not generally. It was tested, but -- but not every time.
Q. And what test was that?
A. There -- the -- What test?
Q. Right.
A. The test for the slippage of the knot.
Q. And how was that test conducted?

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A. Pull tested with the inside i.d. of the suture held and measured the strength before the increase in size of the inner loop.
Q. What type of machine was used for that?
A. Tensile test machine.
Q. Would you draw a picture of that test.
A. (Witness complying).
Q. Okay. Can you label the components you've drawn.
A. (Witness complying).
Q. And can you describe what you have labeled -- I see you have labeled the crosshead, two hooks, the knot, and a suture loop; right?
A. Yes.
Q. Okay. And the forces applied by -- Well, what type of machine is this? I'm sorry. This is a tensile test?
A. Tensile test.
Q. And force is applied to pull from each direction, top and bottom, if you will?
A. That's what the two arrows signify.
Q. Okay. Are there mandrels which that knot -- around that suture loop? Does the suture loop go around mandrels?
A. Hooks or pins or some way to affix the suture. So when you say a mandrel, I mean there's a lot of

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different types of mandrels.
Q. Okay.
A. I'm not sure what you mean.
Q. Something with a hook that the loop wraps around, goes around -- the suture loop goes around?
A. I've got two hooks listed there, yes.
Q. Okay. And you labeled the knot; right?
A. Yes.
Q. And this test is measuring -- Can you explain to me how this test is measuring --
A. Yeah, once the crosshead moves --
Q. Right.
A. -- this is placed under a fixed tension to start with to remove any -- any slack in the loop --
Q. Correct. Okay.
A. -- and then once it's test -- once the crosshead is moved, you measure the tensile strength which is required to increase that loop opening.
Q. Are you pulling on one of the parts of the knot?
A. That's what -- What do you mean parts of the knot? No. The knot's here on the side. Pulling 90 degrees from the knot on both ends.
Here, I'll draw you a bigger picture.
Q. Thank you.
A. (Witness complying).

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Q. Well, the knot that you're describing here, is this knot the same knot as, for example, that you would tie your shoe? You just go over?
A. It's a square knot.
Q. You're calling it a square knot? Okay.
A. Yes. Now you can tie many different knots there.
Q. Right.
A. To determine which knot has the best efficiency with use with that particular type of suture -- there's 30 or 40 different types of knots.
Q. Okay.
A. The test calls for a square knot.
Q. Okay. And when the force is applied, it's measuring -- you want it -- the object here is to determine how much -- or I'm sorry -- the object is to determine when the suture that's tied in this knot starts slipping out of the knot?
A. Yes.
Q. And the force at which it does that is considered the knot -- it's the knot security?
A. Yes.
Q. Okay. Did you analyze the Pearsalls polyester suture for knot security?
A. Yes.
Q. How about the Tevdek suture? Did you analyze

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that for knot security?
A. Yes.
Q. Okay. So in selecting sutures in your experience, knot security, knot strength, tensile strength are all important considerations?
A. Yes.
MR. SOFFEN: Are you going to label that as an exhibit?
MR. BONELLA: Sure. If you would date that and initial that, Mr. Grafton.
We'll mark that as DePuy Mitek Exhibit 421. And that's Mr. Grafton's drawing of the knot security test.
(DePuy Mitek Exhibit No. 421, Mr. Grafton's drawing of the knot security test, was marked for identification.)
Q. The Tevdek suture, was that also polyester?
A. Yes.
Q. And Size 2?
A. Yes.
Q. Any other sizes?
A. Possibly.
Q. But you don't remember?
A. No.
Q. Was the Tevdek suture braided?

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A. Yes.
Q. Did the Tevdek suture have a core?
A. I have no idea.
Q. Why was there a shift -- Let me back up. When Arthrex began selling the Tevdek polyester suture, did it stop selling the Pearsalls polyester suture?
A. Yes.
Q. Why was there a shift from the Pearsalls polyester suture to the Tevdek polyester suture?
A. I answered that question already.
Q. You did? I'm sorry. I missed it. What was the reason?
A. The stiffness and compliance of the suture.
Q. So the Tevdek suture was more compliant --
A. That's correct.
Q. Let me finish the question. The Tevdek suture was more compliant than the Pearsalls polyester suture?
A. That's correct.
Q. Did the Tevdek suture have a coating?
A. Yes.
Q. Do you know what the coating was?
A. No.
Q. And the Pearsalls suture, was the braid constructed on a carrier braider machine?
A. Yes.

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A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they

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compared to the competitive products.
Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength

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and tensile strength; right?
A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr.

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Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."
And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

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A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

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Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

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processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

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this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

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ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

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Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

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Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent. I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

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A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

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MR. SOFFEN: Objection; asked and answered. You've asked him the same thing multiple times. But you can answer.
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.
Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

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A. Yes.
Q. And the prototype of PET and ultra-high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra-high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- Who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with the ultra-high molecular weight polyethylene, was it -- did it have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively).
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?

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Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. And was that part of your initial idea, or was that -- because I thought you said your initial idea was to add the PET. Was it also to coat it, or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.
Q. Okay. But the prototype that was manufactured that you asked --
A. Most likely, it was coated, because it needed to be as the final product would be marketed.
Q. You said most likely. Do you remember or you don't remember whether the prototype that had the PET and the ultra-high molecular weight polyethylene was coated?
A. I can't tell you for sure that it was at that prototype stage.
Q. Okay. Was this prototype that you had -- after you tested the prototype with PET with ultra-high --
A. Excuse me. I want to change that.
Q. Okay.

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A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probability that the suture came as -- the second prototype -- as coated.
Q. That was standard for them to coat it, in other words?
A. Yes.
Q. Okay. So the initial prototype that was ultra-high molecular weight polyethylene, did you ask for that not to be coated?
A. No.
Q. So chances are that that one was coated?
A. Quite possibly.
Q. After you tested the prototype of PET and ultra-high molecular weight polyethylene braided together, did you believe that it would then work as a suture?
A. Yes.
Q. Okay. Is there anything else you think you needed to do in order to determine whether it would work as a suture?
A. Yes.
Q. What did you need to do?
A. Biocompatibility toxicity testing, bioburden levels, all the design control GNP items that need to be

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done on any product. Obviously, there needed to be a check -- there's a checklist -- okay -- so I'm going by memory, that it needed to be looked at from a patent standpoint to see if there was any infringing as well as whether the product was compatible, along with the GNP items that are required for the product.

Q. Okay. Those things you are describing to me, those were all kind of commercial considerations. My question is a little different. Maybe my question wasn't clear. My question was more along the lines of once you had the prototype of the ultra-high molecular weight polyethylene and PET braided together and you tested it and you believed that it would work as a suture, I understand there's things you needed to do to make it a commercial product.

Was there anything else you needed to do in your mind to clarify whether it needed to -- whether it could work as a suture?

A. We needed to have a surgeon look at it that would actually be tying knots with it to get their understanding of -- of how they felt about the suture.

Q. Okay. Anything else though?

A. Not that I recall.

Q. Okay.

MR. SOFFEN: Is it time for a break? In a few

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minutes?

MR. BONELLA: Yeah. Just give me five. Let me just finish this line of questions.

Q. Was the initial prototype that was ultra-high molecular weight polyethylene, was that sterile?

A. I don't remember.

Q. How about the prototype that was PET and ultra-high molecular weight polyethylene braided together? Was that sterile?

A. I don't remember.

Q. Would it have to have been sterile? Would the prototypes have to have been sterile?

A. Not to test on the tensile test machine.

Q. Why not?

A. Because it's not going into a human. You don't -- The bioburden levels at that point is not a factor that was wrong.

Q. Was sterilization another process at that time? Was that something you really didn't have to account for?

A. Say the question again.

Q. I'm just making sure that what you're saying is that sterilization is just to -- was just to -- it's really for biocompatibility? It's not to change the properties of the material; is that right?

MR. SOFFEN: Objection; vague.

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A. I don't know. I don't know. That's really a weird question.

Q. I understand you are saying they weren't sterile.

A. No. I didn't say -- I said I don't recall, sir.

Q. You don't recall?

A. Yes.

Q. Okay. And my question was would they have had to have been, and you said, I think, no because they were testing them for mechanical properties.

A. Yes.

Q. Okay. Did you -- Would the sutures have had to have been sterile when you tested them for mechanical properties?

A. I already answered that.

MR. SOFFEN: Objection; asked and answered.

A. I said no. It didn't have to be to be tested on a tensile test machine.

Q. And why is that?

A. I already answered that also. It's not being used for human or animal use, so the biocompatibility issues of the suture at that time were not looked at. The mechanical features of the suture were all that were looked at at that portion of the prototype stage.

Q. Did sterilization have a big effect on the mechanical properties of the suture, the tensile?

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MR. SOFFEN: Objection.

A. I -- I can't answer that question.

Q. You don't know?

A. No.

Q. But when you made the decision to go forward with this, you can't remember whether they were sterile or not?

A. You asked me -- You're -- you're kind of putting a couple of things together, so that's why you're --

Q. Okay. Maybe I'm getting confused.

A. You asked me if the prototypes were sterile, and I said no.

Q. Okay.

A. The decision to go forward with the product, obviously, there has to be sterilization done before the product can be marketed.

Q. Absolutely. And are you saying that the decision to go forward with it was made before you tested a sterile product?

A. I can't say that.

Q. Do you recall testing a sterile product before the decision was decided to make -- decided to go forward with the PET and the --

A. I don't remember.

Q. -- ultra-high molecular weight polyethylene?

A. I don't -- It depends on what point in time you

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A. I don't recognize this particular exhibit, but it looks like a test report.
Q. Is that your signature on the first page?
A. Yes, it is.
Q. And you signed it on February 13th, 2003?
A. Right.
Q. And the test objective stated was to evaluate US -- I'm sorry -- FiberWire US 3/4 sutures, construction numbers DTPS 21 and DTPS 34 for knot pull, straight pull, and diameter. Do you see that?
A. Yes.
Q. And the previous exhibit, 175, refers to DTPS 21 and 34 and that was in January of '03; right?
A. Yes.
Q. Okay. Looking at Exhibit 422, does that refresh your memory at all as to why Arthrex was evaluating a 100 percent polyester -- I'm sorry. I will rephrase the question.
Looking at Exhibit 422, does that refresh your memory at all as to why Arthrex was evaluating a construct that had 100 percent polyester in the sheath?
A. I don't remember.
Q. You don't remember? In the Observations and Conclusions section of Exhibit 422 on the front, it said, "Also, both the sutures had similar strength in straight

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pull, but knot pull const. DTPS 34 had more strength than DTPS 21. Hence, only construction DTPS 34 is approved for production." Do you see that?
A. Yes.
Q. Do you recall reaching that conclusion?
MR. SOFFEN: Objection. There's no evidence that it's Mr. Grafton's conclusion here, but ...
MR. BONELLA: It's coming.
A. I don't remember the circumstances of this document, so I can't really answer that.
Q. Would you turn to Page ARM 25664.
A. Is that in this document?
Q. Yes. In Exhibit 422. Do you see it's a Pearsalls Limited Certificate of Conformity?
A. Yes.
Q. Do you see that?
A. Yes.
Q. Do you recall seeing these types of documents before from Pearsalls?
A. Yes.
Q. What was your understanding of the purpose of a Certificate of Conformity that Pearsalls would send?
A. It's a cert that goes with the product to give the certifications of how it was tested and what the conformance of it is.

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Q. And that's according -- and those certs are according to the U.S. Pharmacopeia?
A. Yes.
Q. Now does Pearsalls sterilize the products for Arthrex?
A. No.
Q. So these Certificates of Conformity are issued without sterilization?
A. That's correct. In this particular one, yes.
Q. In general, were the Pearsalls --
A. In general, Pearsalls, yes. That was -- that was prior to sterilization when we received the product from Pearsalls.
Q. Did Arthrex do a new Certificate of Conformity after the products have been sterilized?
A. It was tested after sterilization.
Q. Does Arthrex do a new Certificate of Conformity?
A. There was quality control records that would show the test result after sterilization.
Q. And how were those tests -- how were those tests done?
A. Same type of tests, knot, straight pull.
Q. Okay. And were they done for each batch of FiberWire, or did you select a certain sample from each batch? Like how were the tests done after sterilization?

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A. Early on, I'm sure every batch was done. After that, probably not every batch.
Q. Do you recall the results of those tests?
A. No.
Q. What type of sterilization procedure does Arthrex use for FiberWire?
A. ETO and gamma.
Q. And those are known procedures? Are they -- I will ask a better question.
Did Arthrex develop those procedures, the sterilization of ETO and gamma, or were those known procedures in the art?
A. What do you mean by known? ETO and gamma are sterilization methods used in medical products. If that's your definition of known, the answer to that is yes.
Q. Did Arthrex develop anything special about applying those techniques to FiberWire?
A. They depended on how the product was sold. Whether it was sold in an envelope or with a suture anchor, there would be different types of sterilization that Arthrex would have been involved in the development.
Q. What do you mean by depending upon the -- how the product was sold?
A. Whether it was sold with a suture anchor, metal or bioabsorbable, those require different types of

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uncoated but that had gone through the scouring and dye process?
A. I don't remember.
Q. When you tested the coated versus uncoated, do you know whether the coated one that you tested was one that had been dyed --
A. I don't remember that.
Q. -- or undyed? Okay. If it's a -- Okay. Do you recall like any invoices that came back with the samples that you asked for for testing in relation to the Ethicon patent?
A. No. There may not have been invoices.
Q. Do you see inside these packages, there's -- it looks like, at least for this one --
A. Ah, okay. Here. You see this little round section?
Q. Yes.
A. This is most likely the information that was on the round 2-inch spool.
Q. Okay.
A. And this is where somebody xeroxed it on the machine, it looks like, and cut it out, the silhouette of it, and that's what we're looking at there, now that I see it closer.
Q. Okay. Do you see where it says batch? Coated

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MED. At least this one says Coated MED. And it says Batch on it. And it's Exhibit 428.
A. I see the information, yes.
Q. Okay. Do you see the uncoated one has a -- it has a batch number there. Do you see that for the uncoated?
A. Yes.
Q. Is that a Pearsalls batch number?
A. Yes.
Q. And do you see the other number there? There's a -- on the -- it has the number 38A500500? Do you see that number?
A. Yes.
Q. Do you recognize that number?
A. No. It's not an Arthrex number.
Q. Okay. How about the L51211 number? Do you recognize that number?
A. No. Those are all Pearsalls' internal numbers.
Q. Okay. Did you keep any records of the samples that you got from Pearsalls for testing uncoated versus uncoated with respect to the 44 -- with respect to the Ethicon patent of how the samples were to be maintained or kept?
A. I'm sure I turned the samples over to our test group. I don't recall any -- and probably any certs or

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information that were with them, but I didn't keep any of that.
Q. Okay. When you say you turned them over to the test group, do you mean when you left or was that when you completed the coated versus uncoated testing that you did?
A. At the time that the testing was to be done, I would give them the samples and the certifications so they would know which is coated and which is uncoated.
Q. Okay. And did you get the samples back after the testing, or did they remain with the test group?
A. I don't remember.
Q. Okay. I think the question kind of came out fuzzy. I have to reask one of the questions. I misspoke.
Did you keep any records of the samples that you got from Pearsalls for testing coated versus uncoated with respect to the Ethicon patent?
A. Keep any copies of the records?
Q. Yeah.
A. The test results?
Q. No, the records in terms of maintaining the samples, of how the samples were to be maintained or --
A. I turned all of that over to the test department.
Q. Okay.
A. Because they would need that to be able to write up the test report, any information I had.

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Q. Do you know if any of the samples that -- when you tested the coated versus uncoated in relation to the testing for the Ethicon patent, had any of those undergone sterilization?
A. I don't think they had.
Q. Okay. Now in the coating process that Pearsalls uses, there's an oven, and there's some tension applied during that process?
A. Yes.
Q. Right? Do you know if the uncoated sample that you tested in relation to the Ethicon patent had undergone that heat process and the tensioning?
A. They both -- The coated or both?
Q. No, the uncoated.
A. Uncoated?
Q. Right.
A. I'm sure it did not.
Q. Okay.
A. When you are saying heat process, it's to flash off the solvents with -- with the amount of heat is used for.
Q. Are you aware of the temperatures that are used?
A. No.
Q. Are you aware of how long the FiberWire is in the ovens?

HERMES EXPERT REPORT
EXHIBIT 14

US006716234B2

(12) **United States Patent**
Grafton et al.

(10) **Patent No.: US 6,716,234 B2**
(45) **Date of Patent: Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton**, Naples, FL (US); **D. Lawson Lyon**, Exeter (GB); **Brian Hallet**, Taunton (GB)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

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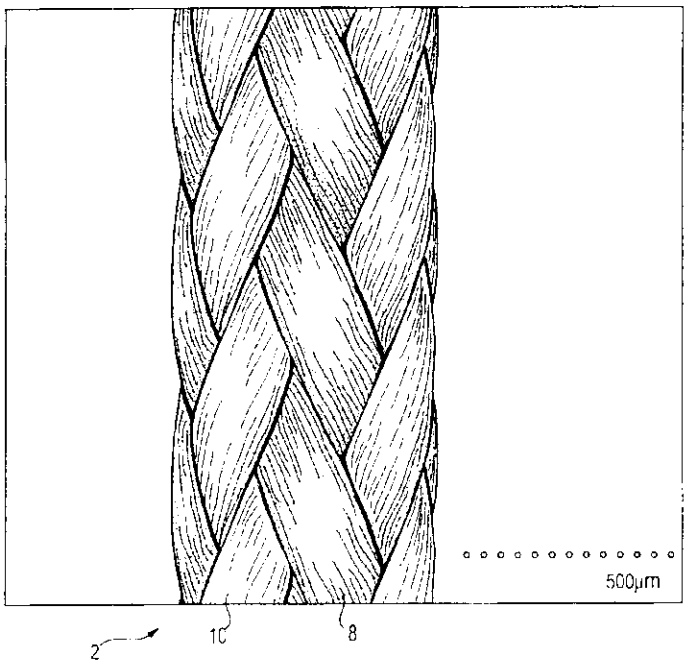
(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



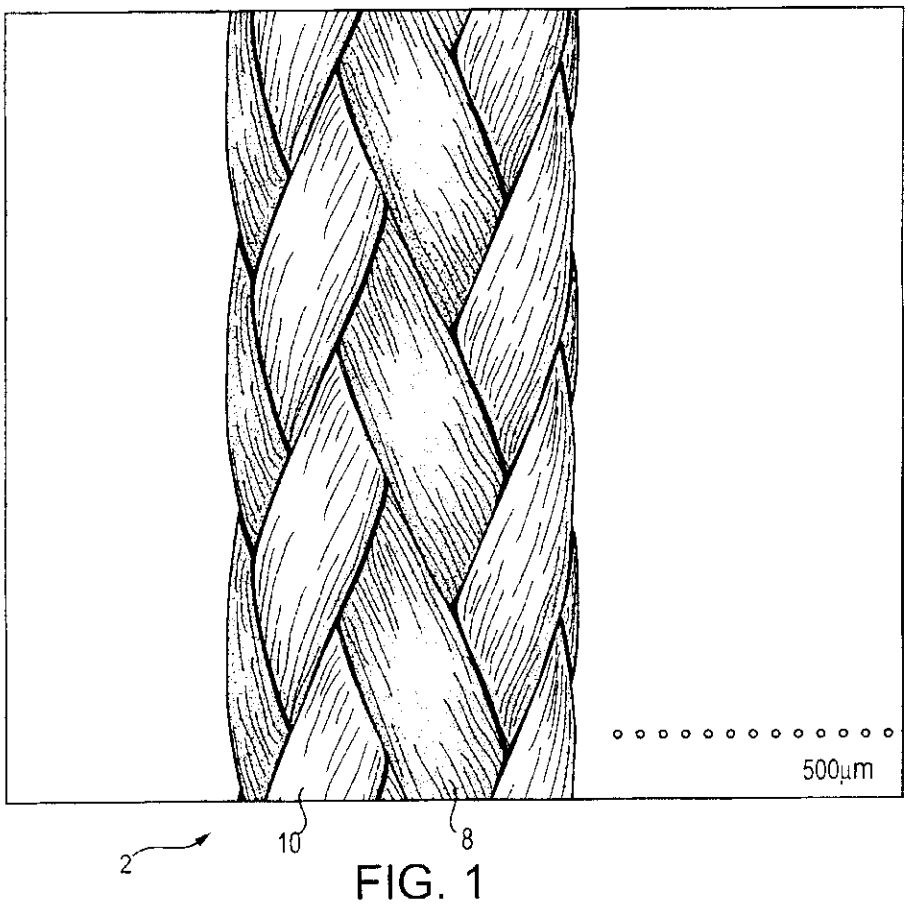


FIG. 1

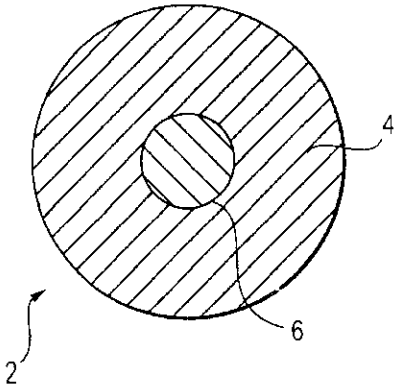


FIG. 2

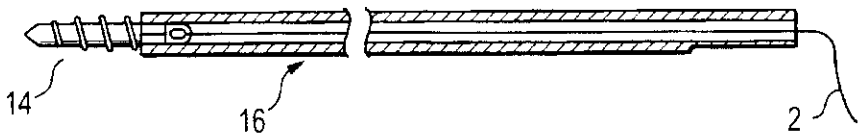


FIG. 3

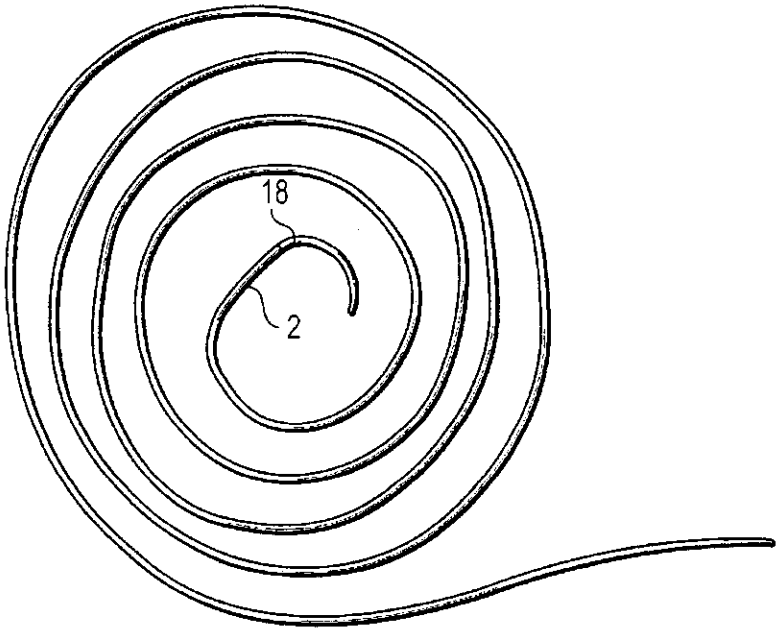


FIG. 4A

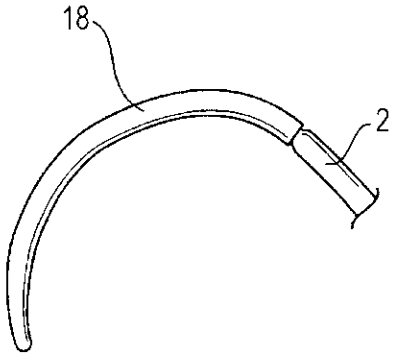


FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. **1** is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. **2** is a schematic cross section of a length of suture according to the present invention.

FIG. **3** is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. **4**A and **4**B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a scanning electron micrograph of a length of suture **2** according to the present invention is shown. Suture **2** is made up of a cover **4** and a core **6** surrounded by the cover. See FIG. **2**. Strands of ultrahigh molecular weight polyethylene (UHMWPE) **8**, sold under the tradename Dyneema or Spectra, and strands of polyester **10** are braided together to form the cover **4**. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim **1**, further comprising a coating disposed on the cover.

7. The suture filament of claim **1**, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *